Emergency Department Attendance towards the End-of-Life by People with Cancer: A Mixed Methods Study

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King's College London

Emergency Department Attendance towards the End-of-Life by People with Cancer: A Mixed Methods Study

A thesis incorporating publications submitted to

King's College London for the degree of Doctor of Philosophy

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July 2017

Abstract

BACKGROUND: Emergency department (ED) visits towards the end-of-life by people with cancer are increasing over time. This is despite an association with poor patient and caregiver outcomes, most patients preferring home-based care, and capacity concerns for many EDs across developed countries. In order to develop appropriate interventions to reduce ED visits, a comprehensive understanding of cancer patients' end-of-life ED use is vital.

AIM: To understand variation in cancer patients' end-of-life (last month) ED use in order to support the development of future initiatives aimed at reducing high attendance and improving equity of access to end-of-life healthcare services.

DESIGN: A mixed methods study with a concurrent triangulation design.

METHODS: Quantitative methods were used to describe cancer patients' end-of-life ED use and investigate socio-demographic, clinical and environmental factors independently associated with multiple (≥2) ED visits towards the end-of-life. These comprised: secondary analysis of pooled data from two mortality follow-back studies: the QUALYCARE study (n=554) and the International Access, Rights and Empowerment (IARE) study (n=127); and, a population-based retrospective cohort study using linked patient-level data from the Office for National Statistics and Hospital Episode Statistics (n=124,030): dataset supplied by NHS Digital. Data was analysed using descriptive statistics, bivariate and multivariable logistic regression. A qualitative interview study explored advanced cancer patients' and their caregivers' decisions to seek ED care. Data was collected through semi-structured patient (n=18) and caregiver (n=6) interviews, and review of patients' healthcare records. Interviews were audio recorded, transcribed verbatim and analysed using a constant comparative approach. Integration occurred at the study's discussion

stage when findings from the quantitative and qualitative components were combined and overall conclusions made.

RESULTS: Pooled data from the mortality follow-back studies comprised 681 cancer decedents (50.1% men; mean age at death 75 years). Of these, 29.7% experienced multiple ED visits during their last three months of life. Community health care services, in particular contact with palliative care, reduced the likelihood of patients experiencing aggressive end-of-life care, including multiple ED visits. The population-based retrospective cohort study identified 124,030 adults who died from cancer in England during a one year period (01/04/11 to 31/03/12). Of these, 30.7% visited the ED once in their last month of life; 5.1% made multiple visits. Patients were more likely to visit the ED multiple times if they were: younger; male (adjusted odds ratio (AOR) 1.26, 95% confidence interval (CI) 1.19-1.34, reference female); Asian or Black (AOR 1.49, 95% CI 1.27-1.74 and AOR 1.21, 95% CI 1.01-1.46 respectively, reference White); of lower socio-economic status (AOR for most deprived quintile 1.19, 95% CI 1.09-1.30, reference least deprived quintile). Clinical characteristics associated with an increased odds of multiple ED visits were a higher co-morbidity score and diagnosis of lung or head and neck cancer (AOR 1.74, 95% CI 1.56-1.95 and AOR 1.67, 95% CI 1.40-2.00 respectively, reference colorectal cancer). Patients with a higher number of previous ED visits were found to have a greater odds of multiple ED visits in the last month of life; this followed a dose–response pattern (*p* for trend <0.001). In the qualitative data, four key issues influencing advanced cancer patients' and their caregivers' decisions to seek ED care emerged: 1. Disease-related anxiety – those with greater anxiety relating to their cancer diagnosis interpreted their symptoms as more severe and/or requiring immediate attention; 2. Prior patterns of health-seeking behaviour – at times of crisis participants defaulted to services they had previously used; 3. Feelings of safety and familiarity with the hospital setting – many felt reassured by the presence of healthcare professionals and

monitoring of their condition; and, 4. Difficulties accessing community healthcare services – especially urgently and/or out-of-hours.

CONCLUSIONS: Socio-demographic (younger age; male sex; Asian or Black ethnicity; low socio-economic status), clinical (high co-morbidity score; diagnosis of lung or head and neck cancer) and environmental (fewer community healthcare services; lack of palliative care; high previous ED use) factors are associated with an increased risk of multiple ED visits towards the end-of-life by people with cancer. Issues influencing advanced cancer patients' and their caregivers' decisions to seek ED care are complementary and propose underlying mechanisms of action for the quantitative associations found. Difficulties accessing community healthcare services and feelings of safety and familiarity with the hospital setting appear to support the quantitative environmental factors, whilst disease-related anxiety may explain some of the variation found in ED use across socio-demographic groups. The findings provide evidence for the development of future interventions to address these aspects. These may include: 1. Early warning systems or screening tools based on the quantitative factors, leading to earlier engagement with relevant services such as palliative care; and, 2. Support for healthcare professionals in exploring patients' interpretation of their symptoms and disease-related anxiety.

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List of Abbreviations

A&E	Accident and Emergency
AOR	Adjusted Odds Ratio
CI	Confidence Interval
COPD	Chronic Obstructive Pulmonary Disease
CRN	Clinical Research Network
ED	Emergency Department
GP	General Practitioner
HES	Hospital Episode Statistics
HSCIC	Health and Social Care Information Centre
ICD	International Statistical Classification of Diseases and Related Health Problems
KCH	King's College Hospital
NHS	National Health Service
NIHR	National Institute for Health Research
NICE	National Institute for Health and Care Excellence
NQF	National Quality Forum
ONS	Office for National Statistics
OR	Odds Ratio
UK	United Kingdom
USA	United States of America
WHO	World Health Organisation

Publications, Presentations and Awards

Abstracts and publications in peer-reviewed journals

Henson LA, Gao W, Higginson IJ, Smith M, Davies JM, Ellis-Smith C and Daveson BA. Emergency department attendance by patients with cancer in their last month of life: a systematic review and meta-analysis. ***Journal of Clinical Oncology:*** *official journal of the American Society of Clinical Oncology* 2015; **33**(4): 370-376.

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Presentations at scientific meetings and conferences

Henson LA, Gao W, Higginson IJ and Daveson BA. Factors associated with emergency department attendance by advanced cancer patients towards the end-of-life: A mixed methods study. Poster presentation at: First annual PhD symposium held jointly between the

Departments of Palliative Care, Policy & Rehabilitation and Psychological Medicine; November 2013; London, UK.

Henson LA, Gao W, Higginson IJ, Smith M, Davies JM, Ellis-Smith C and Daveson BA. Emergency department attendance by patients with cancer in the last month of life: A systematic review and meta-analysis. Poster presentation at: Second annual PhD symposium held jointly between the Departments of Palliative Care, Policy & Rehabilitation and Psychological Medicine; November 2014; London, UK.

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Henson LA, Gao W, Higginson IJ, Smith M, Davies JM, Ellis-Smith C and Daveson BA. Emergency department attendance by patients with cancer in the last month of life: A systematic review and meta-analysis. Poster (S39) presentation at: Spring Meeting for Clinician Scientists in Training 2015, Academy of Medical Sciences; February 2015; London, UK.

Henson LA, Bernstein L, Higginson IJ and Burman R. Emergency department visits towards the end-of-life by patients with cancer: Why do they happen and can they be prevented? Oral presentation at: Medical Grand Round, King's College Hospital; June 2015; London, UK.

Henson LA, Higginson IJ and Gao W. What factors are associated with multiple emergency department visits by patients with cancer in the last 30 days of life? A population-based cohort study. Poster presentation at: Perspectives; Second Annual Joint Conference of Clinical Oncology, Medical Oncology and Palliative Medicine; February 2016; London, UK.

Henson LA, Higginson IJ and Gao W. What factors are associated with multiple emergency department visits by patients with cancer in the last 30 days of life? A population-based cohort study. Oral presentation at: Perspectives; Second Annual Joint Conference of Clinical Oncology, Medical Oncology and Palliative Medicine; February 2016; London, UK.

Henson LA, Higginson IJ and Gao W. What factors are associated with multiple emergency department visits by patients with cancer in the last 30 days of life? A population-based cohort study. Oral presentation at: Third annual PhD symposium held jointly between the Departments of Palliative Care, Policy & Rehabilitation and Psychological Medicine; March 2016; London, UK.

Henson LA, Higginson IJ and Gao W. Factors associated with multiple emergency department visits by patients with cancer in the last 30 days of life: A population-based cohort study. Oral presentation at: European Association of Palliative Care conference; June 2016; Dublin, Ireland.

Ison L, **Henson LA**, Higginson IJ and Gao W. Cancer patients who die in the emergency department: A descriptive study. Oral presentation at: European Association of Palliative Care conference; June 2016; Dublin, Ireland.

Henson LA, Higginson IJ and Gao W. Factors affecting accident & emergency department attendance in the last month of life. Oral presentation at: Excellence in Research and Innovation; King's Health Partners, Surrey Cancer Research Institute and Tata Memorial Centre Joint Cancer Conference; June 2016; London, UK.

Henson LA, Higginson IJ and Gao W. Emergency department attendance towards the end-of-life by people with cancer. Oral presentation at: Palliative Care Multi-Disciplinary Team Education Meeting, Guy's and St Thomas' NHS Foundation Trust; June 2016; London, UK.

Henson LA, Higginson IJ, Daveson BA, Ellis-Smith C, Koffman J, Morgan M and Gao W. 'I'll be in a safe place': A qualitative study of the decisions taken by people with advanced cancer to seek emergency department care. Poster presentation at: Round the clock: Making 24/7 palliative care a reality, a joint meeting between Marie Curie and the Palliative Care Section of the Royal Society of Medicine; October 2016; London, UK.

Awards and Prizes

Henson LA, Higginson IJ and Gao W. What factors are associated with multiple emergency department visits by patients with cancer in the last 30 days of life? A population-based cohort study [abstract]. Perspectives; Second Annual Joint Conference of Clinical Oncology, Medical Oncology and Palliative Medicine; February 2016; London, UK. Winner of best abstract.

Henson LA, Higginson IJ and Gao W. What factors are associated with multiple emergency department visits by patients with cancer in the last 30 days of life? A population-based cohort study [oral presentation]. Third annual PhD symposium held jointly between the Departments of Palliative Care, Policy & Rehabilitation and Psychological Medicine; March 2016; London, UK. Winner of best oral presentation.

Acknowledgements

I would like to thank all the patients and caregivers who participated in this research. Their strength, courage and generosity was humbling.

I would also like to thank my colleagues at the Cicely Saunders Institute. In particular, I wish to acknowledge the support and wisdom received from my PhD supervisors, Dr Wei Gao and Professor Irene Higginson.

I would like to acknowledge Cicely Saunders International and The Atlantic Philanthropies for funding this research as part of project BuildCARE (Building Capacity, Access, Rights and Empowerment). I am truly grateful for the support they provided and without which this study would not have been possible. I would also like to recognise the additional support received from Marie Curie Cancer Care and the Collaboration for Leadership in Applied Health Research and Care (CLAHRC) South London, National Institute for Health Research (NIHR). The CLAHRC is a partnership between King's Health Partners, St George's University London and St George's Healthcare NHS Trust.

Last but not least, thank you to my parents for their endless love and encouragement.

Chapter 1 - Introduction

1.1 Cancer

1.1.1 Definition and Terminology

Cancer is one of the most common causes of morbidity and mortality worldwide (1). Defined by Ruddon (2) as the 'abnormal and unregulated growth of cells which ultimately can invade tissues and metastasise to distant sites' (p. 4), cases of cancer have been described across the globe and throughout time (Figure 1.1) (3, 4).

Figure 1.1: Rembrandt's 'Bathsheba Bathing' (1654).

Oil-on-canvas painting believed to depict early breast cancer by the blue mark painted on Bathsheba's left breast (4).

The term cancer represents a large variety of disease sub-groups. To date more than 200 distinct cancer types have been identified with their classification based on both the underlying cell histology and location within the body. The International Statistical Classification of Diseases and Related Health Problems (ICD), published by the World Health Organisation (WHO), is the

most widely used medical classification of diseases, signs and symptoms, abnormal findings and external causes of injury (5). The tenth (and most recent) revision, ICD-10, contains 12,420 different alphanumeric codes, with Chapter II (Neoplasms: codes C00 – D48) specific to the classification of cancers (6).

1.1.2 Disease Trajectory

In its earliest form cancer represents a focus of abnormal cells in which the process of cell division has become disrupted and unregulated (2). At this initial stage most patients remain physically well, and if present, symptoms tend to be mild and related to the location of the cancer within the body, for example a person with lung cancer may develop a cough. As cell replication continues, malignant cells begin to invade neighbouring structures and/or spread (metastasise) to areas distant from the original site. This stage of cancer varies considerably between individuals and by cancer type. In the advanced and final stages of cancer a relatively rapid deterioration in health generally occurs, regardless of cancer type. This stage is characterised by a precipitous decline in function, greater level of symptom burden and overall reduction in health-related quality-of-life (7, 8). This period of time (weeks to short months) is commonly referred to as the 'end-of-life'.

Compared to other common causes of death, such as heart failure or chronic obstructive pulmonary disease (COPD), the end-of-life decline from cancer is more predictable and sudden acute deaths occur relatively infrequently (7, 9). This more foreseeable end-of-life decline allows healthcare professionals to anticipate death, and therefore engage in timelier – and as a consequence often more meaningful – conversations with patients concerning their preferences for end-of-life care. For many, these discussions provide a valuable gift – the chance to express their wishes and help determine the circumstances of their death.

1.1.3 Epidemiology

In 2012 there were an estimated 14.1 million new cases of cancer, 8.2 million cancer deaths (accounting for approximately 14% of global mortality) and 32.6 million people living with cancer worldwide (10). In the United Kingdom (UK), new cases of cancer were estimated at 327,000 and deaths from cancer at 158,000 (representing approximately 28% of annual mortality) (10).

With the effects of population growth and ageing, mortality from cancer, which is predominantly a disease of older persons, is anticipated to rise further. Between 2012 and 2030 global cancer mortality is predicted to increase by 37% (10), while in the UK, mortality rates are expected to rise 22% from 158,000 deaths in 2012 to an anticipated 193,000 deaths by 2030 (Figure 1.2) (11). Issues pertaining to end-of-life care are consequently affecting a greater number of cancer patients each year, and the importance of providing high-quality care, in accordance with patients' needs and preferences, is increasingly recognised (12).

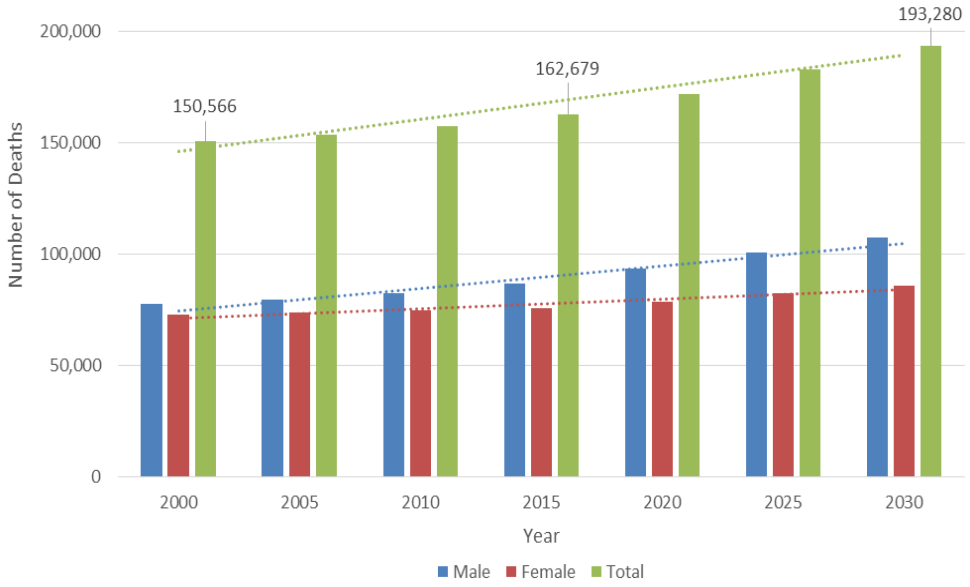

Figure 1.2: Number of UK deaths from cancer (2000 to 2030)

Data based on actual and predicted figures (11)

1.2 End-of-Life Care for People with Cancer

Towards the end-of-life people with cancer wish to be comfortable, be treated respectfully and holistically by healthcare professionals they trust, and have an opportunity to achieve a sense of completion (13-16). Most (64-84%) prefer to be cared for and die at home, and to avoid overly 'aggressive' care, which can be defined as care that focuses mostly, or exclusively, on disease-modifying treatments at the expense of good symptom management and/or advance care planning (14-18).

In England, the importance of providing high-quality end-of-life care has been promoted via a number of initiatives, such as the Gold Standards Framework (19) and the Department of Health's End of Life Care Strategy (20). More recently, the National Institute for Health and Care Excellence (NICE) published an End of Life Care Quality Standard which provides a description of what high-quality end-of-life care should look like (21). However, despite increasing guidance, establishing and evaluating end-of-life care quality is challenging. National Health Service (NHS) England (22) defines high-quality care as that which is 'clinically effective, safe, and provides as positive an experience for patients as possible' (p. 4). Quantifying the quality of healthcare delivered therefore requires the evaluation of patient outcome and/or experience data. In the UK, NHS hospitals now routinely collect certain outcomes data with several measures requiring mandatory reporting to central government health bodies, for example hospital acquired infection rates (23). For oncology services, outcome measures include those relating to cancer waiting times, diagnostic imaging, radiotherapy and chemotherapy (24).

Towards the end-of-life many commonly used outcome measures, such as length of survival, become no longer appropriate, as the focus of care shifts away from life-extending treatments towards maximising the quality of life remaining. Quantifying the intensity or aggressiveness of end-of-life cancer care is especially challenging. Disease-related complications, adverse effects

of treatment and/or unrelated health conditions are all commonly experienced by patients with advanced cancer. In order to be optimally managed, many of these situations require emergency department (ED) care and/or admission to hospital, for example an acutely delirious patient who cannot be managed safely at home. Deciding which visits, investigations and/or treatments represent high-quality end-of-life care versus those that signify overly intensive or aggressive care is difficult, as high-quality care for one patient may be considered overly aggressive by another (25). To address this issue, in 2003, Earle and colleagues developed a set of quality indicators which at a population-level could be used to identify healthcare systems delivering overly aggressive end-of-life cancer care. The process involved a literature review to identify potential indicators of overly aggressive end-of-life care, focus groups with cancer patients and their caregivers to assess these indicators and generate further ideas, and then an expert panel who ranked the meaningfulness and importance of each indicator using a modified Delphi approach (15). The process identified three concepts of poor quality end-of-life cancer care: 1. The institution of new anti-cancer therapies or continuation of ongoing treatments very near to death; 2. A high number of ED visits, in-patient hospital admissions, or days spent in intensive care near the end-of-life; and, 3. A high proportion of patients never enrolled in hospice care, only admitted in the last few days of life, or dying in an acute healthcare setting (15). Further evaluation using Medicare claims data from 48,906 cancer decedents resulted in eight specific performance measures and accompanying benchmarking figures (Table 1.1) (26). With end-of-life care now a recognised component of overall cancer care excellence (12), these performance measures have been adopted throughout the United States of America (USA) and by other countries, for example Qatar, as part of their cancer service monitoring and evaluation (27). In 2012, five of the measures were endorsed by the National Quality Forum (NQF), USA. Collectively, the five measures endorsed focus on the overtreatment of terminally ill patients and utilisation of acute healthcare services towards the end-of-life (28). To date, these

performance measures have not been used to examine the quality of end-of-life cancer care in England.

Table 1.1: End-of-Life Performance Measures

Performance Measure	Benchmark	Sensitivity	Specificity	Accuracy	Variability (95% CI)
Proportion receiving chemotherapy in the last 14 days of life*	<0.10	0.92	0.94	0.92	2.24 (1.74-2.97)
Proportion starting a new chemotherapy regimen in the last 30 days of life	<0.02	0.83	0.94	0.85	3.19 (2.03-5.41)
>1 emergency room visit in the last month of life*	<0.04	0.82	0.96	0.89	2.78 (2.04-3.88)
>1 hospitalisation in the last month of life	<0.04	0.96	1.00	0.97	2.38 (1.85-3.16)
Admission to the ICU in the last month of life*	<0.04	0.87	0.97	0.95	3.28 (2.38-4.67)
Death in an acute care hospital	<0.17	0.95	1.00	0.97	2.49 (2.05-3.12)
Lack of admission to hospice*	<0.45	0.24	0.96	0.88	5.00 (3.76-6.89)
Admission to hospice <3 days before death*	<0.08	0.97	1.00	0.97	2.39 (1.99-2.95)

*Accuracy, the % agreement within +/- 1 day; benchmark, the performance of the top decile of health care service areas; CI, confidence interval; ICU, intensive care unit; sensitivity and specificity refers to claims, compared with medical record review as the gold standard; variability, ration of adjusted rates in the 5th and 95th percentile health care services areas. *Performance measure endorsed by the National Quality Forum, USA (26).*

This study seeks to improve the quality of end-of-life cancer care by focusing on one of these NQF endorsed performance measures – the proportion of cancer patients with >1 ED visit in the last month of life.

Chapter 2 - Background

2.1 The Emergency Department

2.1.1 Definition

Emergency departments (EDs) are medical treatment facilities, typically found in hospitals, which specialise in the urgent and immediate care of those who present without prior appointment. In England, the majority of EDs are 'Type 1' or 'Major' departments. These provide 24-hour consultant led care with full resuscitation facilities and designated accommodation for the receipt of accident and emergency patients (29).

2.1.2 Emergency Department Care

By virtue of the service they provide – discrete episodes of urgent and immediate care – EDs are typically busy, highly pressurised environments; consequently, they are often unsuitable for the delivery of high-quality care to patients with chronic and/or complex medical conditions, such as those with advanced cancer. Continuity of care is lost with presentation to EDs, something valued by advanced cancer patients who would prefer direct admission to an oncology unit or treatment at home if given the choice (30, 31). Studies also suggest that many ED physicians feel under-qualified when treating patients with palliative care needs, many of whom have complex medical requirements that have historically not been part of emergency physician specialist training (32-35). From their analysis of 24 semi-structured qualitative interviews with emergency physician specialist trainees, Stone et al. (32) noted that staff members lacked communication skills to deal with end-of-life care issues and described how ED physicians felt providing end-of-life care to be at odds with their training *"to cure and fix things"* (p. 1334).

Practical issues, for example the risk of exposure to infection, makes the ED environment unsatisfactory for cancer patients, many of whom are immunocompromised due to their advanced disease state and/or treatment. Furthermore, ED overcrowding continues to be a problem despite an association with poor patient and caregiver outcomes and overall dissatisfaction with care (36-38). In a qualitative descriptive study of the experiences of ED overcrowding in Dublin, Ireland, Coughlan and Corry (38) reported one patient describing the experience as: "*like a scene out of a third world country or you know somewhere where a huge disaster had taken place – everyone was crammed into the one area"* (p. 204). The same patient who had attended the ED with a fever following chemotherapy also described the lack of cleanliness: *"he [doctor] had to get down on the floor beside me. The dishes he was using were put on the floor, and it was like the Grand National people jumping over them.....the place was quite grubby"* (p. 204).

From a societal perspective, ED utilisation is of particular relevance due to the high costs associated with providing such care (39-41). The greater expense would be less concerning if it improved outcomes for cancer patients and their caregivers, however, evidence suggests this is not the case. Instead, concerns have been raised regarding the 'high cost of dying' and 'disproportionately' greater healthcare expenditure for cancer decedents than survivors (42-44).

In attempting to reduce overall ED attendance, many NHS immediate care services have undergone substantial change. For example, new general practitioner (GP) walk-in centres, telephone advice services and extended healthcare practitioner roles have all been created (45-49). To date, however, the impact of such initiatives has been limited, and ED attendance has continued to rise (29). In England, the annual incidence of ED visits increased from 12,318,051 in 2007-08 to 18,328,896 in 2012-13; a rise of 32.8% (29). For people with cancer an upward

trend in end-of-life ED visits has also been observed. In Canada, Ho et al. noted that the proportion of cancer patients with multiple ED visits in the last 30 days of life increased from 8.6% in 1993 to 10.5% in 2004 ($p<0.01$) (50). In the USA, Earle et al. reported similar findings with the proportion of cancer patients experiencing multiple end-of-life ED visits increasing from 7.2% in 1993 to 9.2% in 1996 ($p<0.001$) (51).

When considering why these healthcare initiatives have been unable to reduce ED attendance, two key features have been identified:

1) The lack of service-user involvement when developing and implementing new healthcare services (45, 52).
2) An incomplete understanding of the complexity of real world healthcare utilisation by patients and/or their significant others (53).

Healthcare professionals and patients often judge the severity and/or urgency of clinical conditions very differently. In a review of studies investigating 'inappropriate' ED attendance, Penson et al. found that most ED attendees labelled as 'inappropriate' by healthcare professionals thought they were attending appropriately, for example 32% believed they required an X-ray (52). Furthermore, discrepancy between healthcare professionals' and service users' knowledge of the availability of healthcare services was highlighted by Rosenstock, who stated that 'people can only act on what they believe to exist, even though this may not match a healthcare professionals' viewpoint' (54).

To be successful, any future intervention seeking to reduce ED visits must carefully consider service-users' self-perceived needs and understand the complex process by which different factors can influence patients' health-seeking behaviour.

2.2 Health-Seeking Behaviour

Many different factors have been shown to influence patients' decisions regarding the utilisation of healthcare services, and models of health-seeking behaviour can be useful when seeking to understand ED attendance by people with cancer. The most widely acknowledged and arguably most important theory of health-seeking behaviour is the Behavioural Model of Health Services Use developed by Ronald Andersen in 1968 and subsequently published with John F. Newman in 1973 (55). Although initially developed to explain general population non-discriminative healthcare use, the model has since been applied to many different services and/or populations (56-58). The model presents healthcare use as a function of need, enabling resources and predisposing characteristics (Figure 2.1).

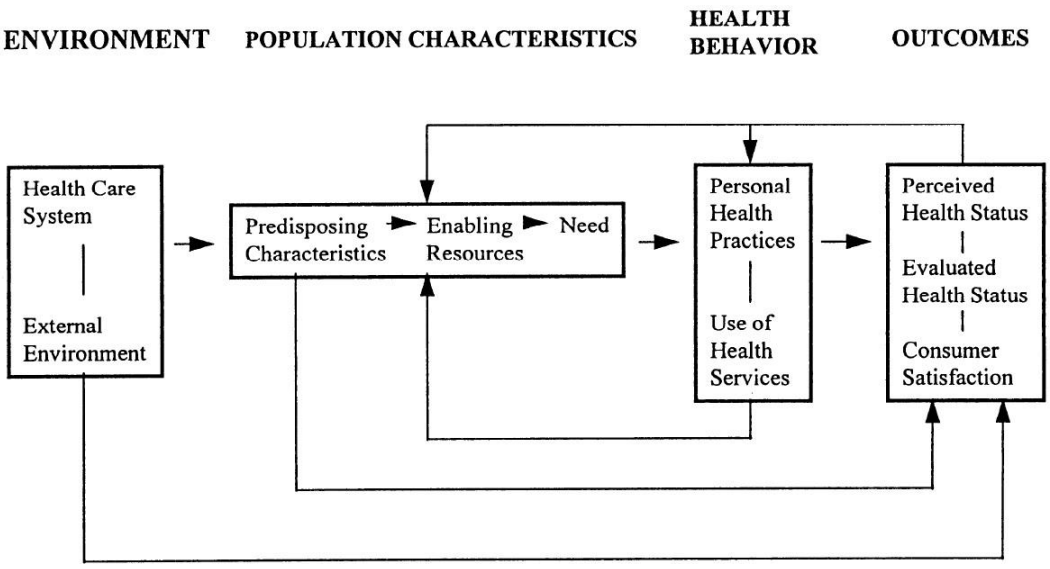

Figure 2.1: Version 4 of Andersen's Behavioural Model of Health Services Use (58)

In addition to Andersen's Behavioural Model of Health Services Use, the Choice-Making Model developed by Young and the Adaptive Decision Maker Model by Payne, Bettman and Johnson, also provide frameworks to explain healthcare use (59, 60). Young's Choice-Making Model was developed from his extensive ethnographic work in two Mexican villages and incorporates

patients' perceptions of their illness, their knowledge and faith in treatment, and their level of access to healthcare resources (59), whereas the Adaptive Decision Maker Model describes how individuals make decisions based on a highly complex system of information processing and weighing-up of alternative options (60). Each of these models identify important concepts that influence patients' use of healthcare services. Whilst none of the models have been applied to people with advanced cancer or at the end-of-life, concepts identified from the models were used as an initial framework from which to further explore the topic of end-of-life ED attendance by people with cancer. This investigation began with a systematic literature review, the aim of which was to identify factors associated with ED attendance by patients with cancer in the last month of life. The findings of this review are presented below in the form of a published paper.

2.3 Emergency Department Attendance by Patients with Cancer in Their Last Month of Life: A Systematic Review and Meta-Analysis [PUBLICATION 1]

VOLUME 33 · NUMBER 4 · FEBRUARY 1 2015

JOURNAL OF CLINICAL ONCOLOGY

REVIEW ARTICLE

Emergency Department Attendance by Patients With Cancer in Their Last Month of Life: A Systematic Review and Meta-Analysis

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Published online ahead of print at www.jco.org on December 22, 2014.

Supported by Cicely Saunders International and The Atlantic Philanthropies, led by King's College London, Cicely Saunders Institute, United Kingdom (BuildCARE).

Authors' disclosures of potential conflicts of interest are found in the article online at www.jco.org. Author contributions are found at the end of this article.

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0732-183X/15/3304w-370w/$20.00

DOI: 10.1200/JCO.2014.57.3568

A B S T R A C T

Purpose
To explore factors associated with emergency department (ED) attendance by patients with cancer in their last month of life.

Methods
Five electronic databases (MEDLINE, EMBASE, CINAHL, PsycINFO, and the Cochrane Library) were searched through February 2014 for studies investigating ED attendance toward the end of life by adult patients (age 18 years or older) with cancer. No time or language limitations were applied. We performed meta-analysis of factors using a random-effects model, with results expressed as odds ratios (OR) for ED attendance. Sensitivity analyses explored heterogeneity.

Results
Thirty studies were identified, reporting three demographic, five clinical, and 13 environmental factors, combining data from five countries and 1,181,842 patients. An increased likelihood of ED attendance was found for men (OR, 1.24; 95% CI, 1.19 to 1.29; I^2, 58.2%), black race (OR, 1.45; 95% CI, 1.40 to 1.50; I^2, 0.0%; reference, white race), patients with lung cancer (OR, 1.17; 95% CI, 1.10 to 1.23; I^2, 59.5%; reference, other cancers), and those patients of the lowest socioeconomic status (SES; OR, 1.15; 95% CI, 1.10 to 1.19; I^2, 0.0%; reference, highest SES). Patients receiving palliative care were less likely to attend the ED in their last month of life (OR, 0.43; 95% CI, 0.36 to 0.51; I^2, 59.4%).

Conclusion
We identified demographic (men; black race), clinical (lung cancer), and environmental (low SES; no palliative care) factors associated with an increased risk of ED attendance by patients with cancer in their last month of life. Our findings may be used to develop screening interventions and assist policy-makers to direct resources. Future studies should also investigate previously neglected areas of research, including psychosocial factors, and patients' and caregivers' emergency care preferences.

J Clin Oncol 33:370-376. © 2014 by American Society of Clinical Oncology

INTRODUCTION

The importance of delivering high-quality, end-of-life care (EoLC) for people with cancer is increasingly recognized. However, establishing and evaluating quality is still a challenge. Multiple (more than one) emergency department (ED) visits by patients with cancer in their last 30 days of life is a recognized indicator of overly aggressive care, the prevalence of which is a potential marker of poor quality.[1,2] There is no evidence that overly aggressive EoLC improves life expectancy, and such care is associated with a reduced quality of life for patients and their families.[2-5] From a societal perspective, overly aggressive EoLC increases demand on already stretched services and increases overall health care costs.[6] Yet, despite the potential negative impact to individuals and society, multiple ED visits by cancer patients in their last 30 days of life has increased over time.[7,8]

Most patients with cancer prefer home-based care[9,10] and value health care provider continuity toward the end of life (EoL).[11,12] EDs are typically hectic, and practical issues such as exposure to infection makes them unsatisfactory for many patients with advanced cancer who are often immunocompromised as a result of their disease and/or treatment. Studies also suggest that many ED physicians feel underqualified to treat palliative care patients, who typically have complex and extensive care needs that have historically not been part of emergency physicians' specialist training.[13-16]

At present, there is limited understanding of the multiple factors that influence advanced cancer patients' use of health care services, especially in relation to the ED. Most of the evidence currently available comes from studies investigating EoLC more generally and often lacks generalizability to settings or populations beyond that of the study in question. Interpretation of study findings is further complicated by the variation in reporting outcomes used. Many ED visits are appropriate and necessary toward the EoL, so understanding the clinical relevance from studies that use an outcome measure that combines single and multiple ED visits can be challenging. However, despite these issues, current financial health care constraints have necessitated policy and services to evolve immediately, especially those that can reduce ED attendance.[17]

To address this, we conducted a comprehensive systematic review and meta-analysis exploring factors associated with ED attendance by cancer patients in their last month of life (both single and multiple ED visits were explored). Building on previous models of health care utilization,[18] as well as those specific to the discipline of palliative and EoLC,[19] we used the findings to develop a conceptual model.

METHODS

Eligibility Criteria

Participants were deceased adults (≥ 18 years old) with any type of malignant cancer. Patients with benign tumors or whose diagnoses were made postmortem were excluded. Eligible studies investigated factors associated with ED attendance by patients with cancer. Studies specifically and only reporting ED visits secondary to complications from chemotherapy, radiotherapy, or cancer-related surgery were excluded, as were studies reporting emergency attendances to other institutions such as hospices. The primary outcome was multiple (more than one) ED visits in the patient's last 30 days of life. Secondary outcomes included at least one ED visit in the patient's last 30 days of life, and single or multiple ED visits for specified time periods within the last 30 days of life. There was no control group for the review. All study designs were included, except case reports and series, review articles, and studies reporting nonoriginal data.[20]

Information Sources

We searched five electronic databases (MEDLINE, EMBASE, CINAHL, PsycINFO, and the Cochrane Library) from inception to February 2014, using a combination of medical subject headings and title/abstract keywords (Data Supplement).[21] No time or language restrictions were applied. In addition to database searching, we scanned reference lists of key studies and performed citation tracking (forward) of the Earle et al (2003)[1] article.[22]

Study Selection

A review author (L.H.) screened all titles and abstracts and excluded irrelevant papers. Two review authors (L.H. and C.E.S. or J.D.) independently assessed the full texts of all the remaining studies. Disagreements regarding three studies were resolved via discussion.

Data Collection Process

Data was extracted from all included studies (by L.H.) using a data extraction spreadsheet developed specifically for the review. Review authors (C.E.S., J.D., and M.S.) independently checked for accuracy and completeness a random sample of 20% of the data extraction forms.

We collected data items that included characteristics of the study population (sex, age, race, marital status, type of cancer, disease stage, level of comorbidity, rurality, and socioeconomic status [SES]), study inclusion and exclusion criteria, detailed description of any factor associated with ED attendance (country, health care system, community services, measures of continuity of care, palliative care services, timing of palliative care services, and advance care planning), and the outcome measures of interest.

Assessment of Risk of Bias

A review author (L.H.) used the validated review tool QualSyst[23] to assess all studies for risk of bias. A random 10% of the assessments were independently checked for accuracy and completeness by review authors (C.E.S. and J.D.). Two additional members of the research team (B.D. and G.W.) resolved disagreements regarding two studies (< 7%) with further independent assessments.

Summary Measures and Synthesis of Results

During piloting of search terms, the most frequently encountered studies were those describing ED attendance with relation to multiple independent variables. ED attendance was mostly reported as a dichotomous outcome with measures of association reported statistically as relative effects using odds or risk ratios. For each factor identified by our review, we assessed the variability in definition across studies and the potential significance of this. Where factor diversity across studies was considered too great, and/or there were too few studies to make quantitative analysis appropriate, we analyzed the factors and reported descriptively. For factors deemed appropriate for statistical synthesis, the pooled odds ratio (OR) and its 95% CI was used as the main summary measure of effect. Where ORs were not published, we either calculated them from patient-level data (n = 14) and/or we contacted study authors to provide the information (n = 7). In the case of no event in the control or intervention group, 0.5 was added to all cells to allow calculation of ORs. A random-effects model based on the Der-Simonian and Laird methods was chosen for all meta-analyses,[21] as study heterogeneity meant that the true effect size was expected to vary between studies. A P value less than .01 was considered significant.[24] Heterogeneity was assessed using I^2. For studies where considerable heterogeneity was identified ($I^2 \geq 50\%$),[25] the meta-analysis was rerun, excluding one study at a time, to test each study's effect on heterogeneity.[21] Sensitivity analysis also examined summary effects according to the following prespecified variables: risk of bias (overall quality assessment [high, medium, or low]), type of cancer, and sample size. Subgroup analysis compared summary effects between studies using the outcome measure of more than one ED visit in the patient's last 30 days of life and those using the outcome measure one or more ED visit in the last 30 days of life. We used funnel plots to assess for publication bias (Data Supplement).[26,27] Stata/IC 13 (STATA, College Station, TX) was used for all statistical analyses.

RESULTS

Study Selection

Thirty-eight references, comprising data from 30 individual studies, were included in the final review (Fig 1). Electronic database searching identified 6,143 references, and an additional 34 studies were identified through the additional search methods described under Information Sources. Deduplication and title/abstract screening excluded 6,073 references, leaving 104 articles for which the full texts were retrieved. Sixty-six articles were excluded by full-text screening; 46 studies were not related to patients' last month of life, 12 did not report any relevant outcomes, three reported nonoriginal data, and one reported emergency admissions to a hospice. Six studies were conducted in populations of patients with both cancer and noncancer diagnoses[28-33] and we attempted to gain further information from all study authors. Four authors replied to our e-mail requests but were unable to supply the supplementary data,[28-30,33] and we could not contact the authors of two studies.[31,32] Two of the studies were included in the final review because in both studies at least 75% of the study populations were patients with a cancer diagnosis.[28,29] The remaining four studies were excluded.

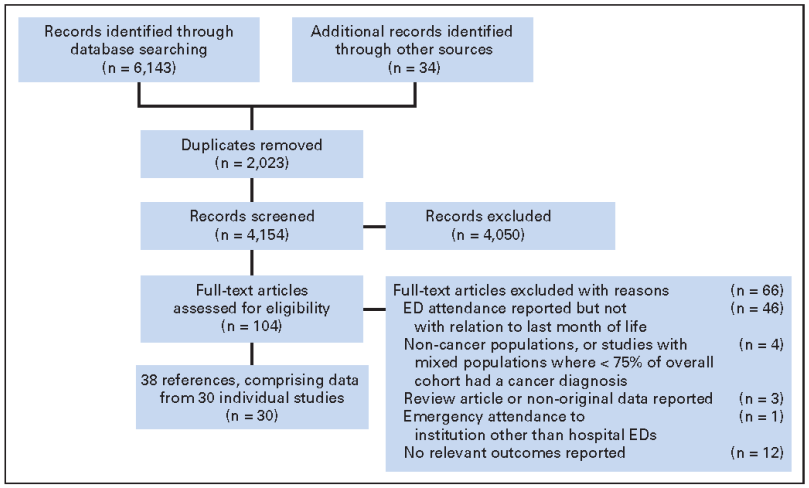

Fig 1. Flow diagram. ED, emergency department.

The Data Supplement summarizes the characteristics, key findings, and risk of bias assessments for all 30 studies included in the review. Combined, the studies report data from 1,181,842 patients, with populations ranging from 40 to 235,821 (median, 5,604 patients). The majority of studies report data from the United States (n = 18) or Canada (n = 8), and 18 studies (60%) use the reporting outcome of more than one ED visit in the patient's last 30 days of life. Twenty-one different factors associated with ED attendance were reported across studies and these have been categorized as demographic, clinical (changes occurring because of disease), or environmental (including both micro-level [individual] and macro-level [social] variables).

Demographic Factors

Sex. Ten studies, all of high-quality, investigated the effect of sex on ED attendance in the patient's last month of life.[7,8,29,34-40] Findings were consistent across studies, with all ten reporting an increased risk for ED attendance by men compared with women (pooled OR, 1.23; 95% CI, 1.18 to 1.28; I^2, 82.3%). Findings were similar for meta-analysis of studies using only the primary reporting outcome of multiple ED visits in the last 30 days of life (n = 5; pooled OR, 1.20; 95% CI, 1.14 to 1.27; I^2, 84.2%). Sensitivity analysis identified two studies that had large effects on heterogeneity. However, excluding these studies, both individually and together, did not affect the overall effect size or direction (pooled OR, 1.24; 95% CI, 1.19 to 1.29; I^2, 58.2%).

Race. Four studies, all high quality and using the reporting outcome measure of multiple ED visits in the patient's last 30 days of life, investigated the effect of race on ED attendance.[7,39,41,42] We found that black people had a significantly higher risk of attending the ED in the patient's last 30 days of life compared with white people (pooled OR, 1.50; 95% CI, 1.35 to 1.66; I^2, 73.2%). Sensitivity analysis identified one study that contributed significantly to heterogeneity; removing this study reduced the effect size but not the overall direction or significance, (pooled OR, 1.45; 95% CI, 1.40 to 1.50; I^2, 0.0%).

Age. Nine studies (including one unpublished) investigated the effect of age on ED attendance.[7,29,34,37,39,40,43,44] Seven studies were graded as high-quality, one was medium, and one was low. Results are reported descriptively as statistical synthesis was not possible owing to the variation in age categories used across studies. We found a consistent finding across all seven high-quality studies of patients in older age categories having a lower risk of ED attendance; this was statistically significant in four of the studies.

Clinical Factors

Cancer diagnosis. Six studies, all high-quality, investigated cancer diagnosis and ED attendance in patients' last month of life.[7,8,34-36,40] The types of cancer investigated and the reporting outcomes used varied across studies. Patients with lung cancer were used as the reference group for five of the studies. We found an increased risk of ED attendance by patients with lung cancer compared with other cancers (pooled OR, 1.17; 95% CI, 1.10 to 1.23; I^2, 59.5%). Two studies had large effects on heterogeneity, however, exclusion did not affect the overall effect size or direction (pooled OR, 1.17; 95% CI, 1.13 to 1.21; I^2, 0.0%). Only two studies used the reporting outcome of multiple ED visits in the patient's last 30 days (pooled OR, 1.14; 95% CI, 1.07 to 1.21; I^2, 76.2%).

Symptoms. Two studies described symptoms experienced by patients with cancer visiting the ED toward their EoL.[45,46] Geraci et al[45] found dyspnea to be the presenting symptom in 43% of cancer patients who attended the ED in their last 2 weeks of life. Leak et al[46] categorized cancer patients' chief complaints at presentation to the ED and found respiratory (17.6%), gastrointestinal (16.2%), and neurologic (14.1%) symptoms were most frequently reported by patients who subsequently died in the ED.

Comorbidities. Six studies (including one unpublished) investigated cancer patients' level of comorbidity and ED attendance.[8,29,34,37,40] All studies were graded as high-quality. Five studies used the Charlson score (or Deyo modification) to assess level of comorbidity,[47,48] whereas Maddison et al[37] used the Elixhauser score, which represents a sum of all comorbid conditions, excluding cancer, in the two years before diagnosis. Findings were mixed. Three studies reported a greater risk of ED attendance with increasing comorbidity

and three studies reported no association, however, further assessment and interpretation was limited owing to the considerable variation across studies in the categorization of patients' comorbidity.

Stage of disease. One study investigated disease stage at diagnosis and found no significant association with one or more ED visit in the patient's last 30 days of life.[37]

Chemotherapy. Keam et al[49] reported that the proportion of cancer patients with more than one ED visit in their last month of life was significantly higher for patients who continued chemotherapy within 2 months of death compared with those who discontinued chemotherapy at least 3 months before death ($P = .002$).

Environmental Factors

Micro-level (individual) variables: socioeconomic status. Five studies, all high-quality, compared the effect of SES on ED attendance toward the patient's EoL.[8,29,34,37,40] We found patients with a higher SES had a reduced risk of ED attendance (pooled OR, 0.87; 95% CI, 0.84 to 0.91; I^2, 0.0%; reference group, lowest SES). Subgroup analysis according to outcome measure (any ED visit [at least one] *v* multiple visits [more than one]) did not demonstrate any differences in the odds of ED attendance.

Micro-level (individual) variables: rurality. Six studies described an association between living in a rural or urban environment and ED visits by cancer patients in their last month of life.[7,8,29,34,37,40] Five studies found patients with cancer living in a rural environment had an increased risk of ED attendance.[7,8,29,34,40] In contrast, Maddison et al[37] found patients with cancer living in an urban environment had a significantly greater risk of ED attendance (adjusted OR, 3.18; 95% CI, 2.0 to 5.1). All studies were graded as high-quality, however, significant heterogeneity (I^2, 94.1%; which when further explored included varying definitions of rural or urban environments) meant that statistical pooling of data was not appropriate and was potentially misleading.

Macro-level (social) variables: country. Warren et al[50] compared cancer care in patients' last 30 days of life in government-financed health-insurance systems in the United States and Canada. The study was conducted in patients ages ≥ 65 years with non–small-cell lung cancer and found SEER-Medicare patients had significantly fewer ED visits in their last 30 days of life than patients in Ontario, Canada (rate difference, 23.3 per 100 person-months; 99% CI, 17.9 to 29.6; $P < .001$).[50]

Micro-level (individual) variables: living circumstances. Maddison et al[37] found patients who were long-term care residents had a reduced risk of attending the ED in their last month of life, though this was not statistically significant (OR, 0.44; 95% CI, 0.2 to 1.2).

Micro-level (individual) variables: marital status. One study (unpublished data) investigated the effect of marital status on ED attendance. Single patients were found to be less likely to have more than one ED visit in their last month of life compared with married patients (adjusted OR, 0.87; 95% CI, 0.85 to 0.92). The findings for divorced/separated and widowed groups were not significant when compared with married patients (adjusted OR for divorced/separated, 0.99; 95% CI, 0.94 to 1.04; adjusted OR for widows/widowers, 1.01; 95% CI, 0.98 to 1.04).

Macro-level (social) variables: palliative care services. The effect of palliative care services on ED visits in patients' last month of life was reported in seven studies.[34,37,38,51-54] Six were graded as high-quality and five used the reporting outcome of multiple ED visits in patients' last 30 days of life. We found cancer patients receiving palliative care services had, on average, a 50% reduction in their odds of ED attendance in their last month of life compared with those not receiving palliative care (pooled OR, 0.50; 95% CI, 0.40 to 0.63; I^2, 87.8%). Subgroup analysis according to outcome measure demonstrated a larger effect size for studies reporting multiple ED visits in patients' last month of life (pooled OR, 0.43; 95% CI, 0.36 to 0.51; I^2, 59.4%) compared with studies reporting at least one ED visit (pooled OR, 0.61; 95% CI, 0.55 to 0.66; I^2, 0.0%).

Six studies investigated the timing of palliative care referral (including one pilot study).[37,51,53,55-57] Findings are reported descriptively because of variations in the referral times compared across studies. Three studies, all high-quality, used the reporting outcome of multiple ED visits in patients' last 30 days of life. Saito et al[51] found patients with non–small-cell lung cancer who had a claim for hospice care at least three days before death had an increased risk of ED attendance in their last month of life (OR, 3.86; 95% CI, 3.76 to 3.97; reference group, hospice claim < 3 days before death). Gonsalves et al[53] found patients who were referred to palliative care more than 2 weeks before death were less likely to visit the ED in their last 30 days of life (OR, 9.84; 95% CI, 9.58 to 10.12; reference group, referral ≤ 2 weeks before death). In contrast with these two studies, in a small study of patients with gynecologic cancers (n = 100), Nevandusky et al,[55] found an increased risk of ED attendance by patients referred to palliative care ≥ 30 days before death (OR, 19.3; 95% CI, 18.7 to 19.8; reference group, referral < 30 days before death).

Macro-level (social) variables: end-of-life discussions. Two studies explored the impact of EoL discussions on ED visits.[58,59] Lopez-Acevedo et al[58] found a reduced risk of multiple ED visits in patients' last 30 days of life by patients with ovarian cancer who had an EoL discussion ≥ 30 days before death (OR, 0.14; 95% CI, 0.14 to 0.15). However, the study was relatively small (n = 220), as was the total number of ED visits reported (n = 3). In a larger study by Mack et al[59] (n = 1,231), patients with stage IV lung or colorectal cancer who had an EoL discussion ≥ 30 days before death were found to have a reduced risk of more than one ED visit in their last 30 days of life (OR, 0.37; 95% CI, 0.36 to 0.38).

Macro-level (social) variables: community services. A number of different community services were investigated in relation to ED attendance at the EoL, including homecare services,[28,29,34,40] general practitioner house calls,[34] nursing care,[29,40] and an interdisciplinary cancer support team.[60] Results for each study are reported in the Data Supplement.

Macro-level (social) variables: healthcare provider. Two studies described an association between patients' main health care provider (HCP) and ED visits at the EoL.[35,61] Conducted across all cancer groups, Tang et al[35] found a reduced risk of ED attendance by patients with an oncologist as their main HCP (adjusted OR, 0.88; 95% CI, 0.81 to 0.96; reference group, care from any other HCP). Consistent with this finding, Murray et al[61] reported reduced EoLC intensity, including number of ED visits, by patients who had an oncologist as their main HCP compared with care by a primary care physician only or joint care delivered by oncology and primary care physicians.

Almaawiy et al[40] explored continuity of care by HCPs and found patients with high HCP continuity of care scores were less likely to attend the ED in their last 30 days of life (adjusted OR, 0.59; 95% CI, 0.52 to 0.66; reference, low continuity of care score).

Macro-level (social) variables: health care system. Keating et al[41] investigated health care systems within the United States. The study

found an increased risk of multiple ED visits in patients' last 30 days of life for fee-for-service Medicare patients compared with US Department of Veterans' Affairs' patients.

DISCUSSION

Bringing together data from 30 original studies and more than one million patients, our review has identified three demographic, five clinical, and 13 environmental factors associated with ED attendance by patients with cancer in their last month of life. Findings were used to develop a conceptual model demonstrating their effect (Data Supplement).

We found consistent and high-quality evidence for an increased risk of ED attendance by men, black people, patients with lung cancer, and those of low SES. Knowledge of high-risk patient characteristics can help policy-makers plan services; these characteristics are important when considering the development of future health care interventions, such as screening or early-warning systems. Screening tools are validated approaches to reducing poor outcomes in health care and have shown to be effective across numerous clinical disciplines.[62-64] A tool that could help identify particularly vulnerable cancer patients, such as those at risk of overly aggressive EoLC, could lead to improvements in patient outcomes through various processes, such as triggering a palliative care referral. Screening tools can also be beneficial by encouraging a more proactive model of care. For many cancer patients, palliative care continues to be delayed until all other oncology options have been exhausted, with evidence that many HCPs, including oncologists, continue to perceive palliative care as incompatible with active cancer therapy.[65,66] A screening tool may help overcome some of these access barriers, including gatekeeping, while also encouraging a more collaborative approach toward patient care.

We found lower quality and/or inconsistent evidence for the effect of several additional factors, and hypotheses can be generated that the following demographic factor (older age), clinical factors (type of cancer, absence of dyspnea, and increasing comorbidity), and environmental factors (increased home care or nursing services, urban place of residence, oncologist as main HCP, and EoLC discussion) may also be associated with a lower risk of ED attendance. In the case of several factors (country, living in a long-term care facility, marital status, GP visits, cancer support team, and health care system), only one study was found in the literature specifically relevant to our review, suggesting that additional research is required to fully understand the complexity of terminal cancer patients' emergency care needs.

Our finding that patients with cancer who are receiving palliative care have a significantly reduced risk of multiple ED visits in their last 30 days of life has added further high-quality evidence to the scientific literature demonstrating the benefits that can be gained from palliative care.[67-69] We have also added to the small but growing body of evidence supporting improved patient outcomes with earlier palliative care involvement.[56,70] However, our review has drawn attention to the highly significant variation regarding models of palliative care delivery. Of the five studies that investigated the timing of palliative care referral, all five defined earlier referral using different time periods, ranging from 3 to 60 days. Palliative care has expanded significantly over recent years.[71] Many services have grown in relative isolation, responding to local need, and initially with little guidance from recognized standards or benchmarking data. Consequently, though national guidance regarding palliative care components are available in some countries such as the United States, internationally, models of palliative care now vary significantly and the optimal delivery model is presently unclear.[72] This may compromise the ways in which community and hospital services can integrate and makes future service planning more complex.

Our review has several limitations. Heterogeneity was managed through meta-analysis using a random-effects model and sensitivity analyses. Despite this, in some cases, heterogeneity remained considerable ($I^2 > 50\%$). This is a common challenge when conducting systematic reviews, with approximately 25% of all meta-analyses having $I^2 > 50\%$.[25]

Although the factors identified provide important information on association, causality cannot be inferred. In addition to this, the estimates reported are a combination of univariable and multivariable effects (having been dependent on the data available), which limits the conclusions that can be made as the interaction between factors cannot be readily determined.

Studies exploring the effect from psychological factors such as patient depression or caregiver distress were identified, but none fulfilled the review's inclusion criteria. There was also a lack of studies investigating patients' and/or caregivers' preferences for health care services and a concentration of studies from the United States. It is therefore likely that important personal and psychological factors are under-represented or missing in our review, and there is scope for additional studies internationally.

The variation in reporting outcomes was managed through subgroup analysis wherever possible, however, the synthesis and interpretation of data for some factors was affected. Finally, population trends can only ever be a guide for the care that any individual will require at the EoL. At times, the ED is the most appropriate setting for urgent care needs to be investigated and managed, and the importance of providing individualized patient-centered care, including ED care if required, must not be overlooked.

Our review has identified demographic (men and black race), clinical (lung cancer), and environmental (low SES and no palliative care) factors associated with an increased risk of ED visits (single and multiple) in the last month of life of patients with cancer. These findings may be used to develop screening interventions for high-risk cancer patients and also provide evidence to assist policy-makers when allocating limited resources for maximal impact. Future studies should investigate areas neglected in previous research, including psychosocial factors and patients' and caregivers' preferences for emergency care services.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Disclosures provided by the authors are available with this article at www.jco.org.

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Emergency Department Attendance by Patients With Cancer in Their Last Month of Life: A Systematic Review and Meta-Analysis

The following represents disclosure information provided by authors of this manuscript. All relationships are considered compensated. Relationships are self-held unless noted. I = Immediate Family Member, Inst = My Institution. Relationships may not relate to the subject matter of this manuscript. For more information about ASCO's conflict of interest policy, please refer to www.asco.org/rwc or jco.ascopubs.org/site/ifc.

Lesley A. Henson
No relationship to disclose

Wei Gao
No relationship to disclose

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No relationship to disclose

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No relationship to disclose

Joanna M. Davies
No relationship to disclose

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No relationship to disclose

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No relationship to disclose

Acknowledgment

We thank all the collaborators and advisors, including service-users. BuildCARE is supported by Cicely Saunders International and The Atlantic Philanthropies, led by King's College London, Cicely Saunders Institute, Department of Palliative Care, Policy and Rehabilitation, United Kingdom. Chief investigator: Irene J. Higginson; grant leads: Irene J. Higginson, Paul McCrone, Charles Normand, Peter Lawlor, Diane Meier, Sean Morrison; project coordinator/primary investigator (PI): Barbara A. Daveson; study arm PIs: Steve Pantilat, Lucy Selman, Charles Normand, Karen Ryan, Regina McQuillan, Sean Morrison, Barbara A. Daveson. BuildCARE members: Emma Bennett, Francesca Cooper, Barbara A. Daveson, Susanne de Wolf-Linder, Mendwas Dzingina, Clare Ellis-Smith, Catherine J. Evans, Taja Ferguson, Lesley A. Henson, Irene J. Higginson, Bridget Johnston, Paramjote Kaler, Pauline Kane, Peter Lawlor, Paul McCrone, Regina McQuillan, Diane Meier, Sean Morrison, Fliss E. Murtagh, Charles Normand, Caty Pannell, Steve Pantilat, Anastasia Reison, Karen Ryan, Lucy Selman, Melinda Smith, Katy Tobin, Rowena Vohora, and Gao Wei.

1: Database search details and search terms used for review

- MEDLINE via Ovid (1946 to February Week 2 2014)
- EMBASE via Ovid (1980 to 2014 Week 07)
- PsycINFO via Ovid (1806 to February Week 2 2014)
- CINAHL via EBSCOhost (Date Run: February 20, 2014)
- The Cochrane Library (Date Run: 20/02/14) - containing the following databases:
    - Cochrane Database of Systematic Reviews (CDSR)
    - Cochrane Central Register of Controlled Trials (CENTRAL)
    - Cochrane Methodology Register
    - Database of Abstracts of Review of Effects
    - Health Technology Assessment (HTA) Database
    - NHS Economic Evaluation Database (NHSEED)

Subject Headings			
MEDLINE	• palliative care • hospice care • hospices • terminal care • terminally ill • neoplasms	• patient admission • patient readmission • hospitalization	• emergency service, hospital • trauma centers • emergency medical services • triage
EMBASE	• cancer palliative therapy • palliative therapy • terminal disease • terminal care • terminally ill patient • hospice • hospice care • hospice patient • neoplasm	• hospital admission • hospital readmission • hospitalization • hospital utilization	• emergency ward • emergency health service
PsycINFO	• palliative care • hospice • terminal care • terminally ill patients • “death and dying” • neoplasms	• hospital admission • hospitalization • health care utilization	• emergency services
CINAHL	• palliative care • hospices • hospice care • hospice patients • terminal care • terminally ill patients • neoplasms • cancer patients	• hospitalization • patient admission • readmission • emergency patients	• emergency care • emergency service • trauma centers • emergency medical services • triage
The Cochrane Library	• palliative care • terminal care • hospices • hospice care • neoplasms • terminally ill	• hospitalization • patient admission • patient readmission	• emergency medical services • admitting department, hospital

			• emergency service, hospital • triage

Title/ Abstract Search Terms		
advanc$ aggressiv$ stage$ progressiv$ terminal$ **ADJACENT WITHIN 3 WORDS OF** diagnos$ diseas$ ill$ **OR** neoplas$ oncolog$ palliat$ hospice$ terminal$ EOL cancer$ carcino$ maligna$ tumor$ tumour$ **OR** (end **ADJACENT WITHIN 2 WORDS OF** life)	use$ utili$ present$ visit$ attend$ admit$ admis$ readmi$ re-admi$ **ADJACENT WITHIN 3 WORDS OF** hospital$ service$ emerg$ inpatient$ in-patient$	(accident **ADJACENT WITHIN 1 WORD OF** emergency) **OR** assessment emerg$ trauma triage **ADJACENT WITHIN 3 WORDS OF** department$ room$ service$ unit$ center$ centre$ ward$

2: Medline (OVID) search strategy

1 (palliative care or hospice care or hospices or terminal care or terminally ill or neoplasms).sh.

2 ((advanc$ or aggressiv$ or progressiv$ or stage$ or terminal$) adj3 (diagnos$ or diseas$ or ill$)).ti,ab.

3 (neoplas$ or oncolog$ or palliat$ or hospice$ or terminal$ or EOL or cancer$ or carcino$ or (end adj2 life) or maligna$ or tumor$ or tumour$).ti,ab.

4 1 or 2 or 3

5 (patient admission or patient readmission or hospitalization).sh.

6 ((use$ or utili$ or present$ or visit$ or attend$ or admit$ or admis$ or readmi$ or re-admi$) adj3 (hospital$ or service$ or emerg$ or inpatient$ or in-patient$)).ti,ab.

7 5 or 6

8 (emergency service, hospital or trauma centers or emergency medical services or triage).sh.

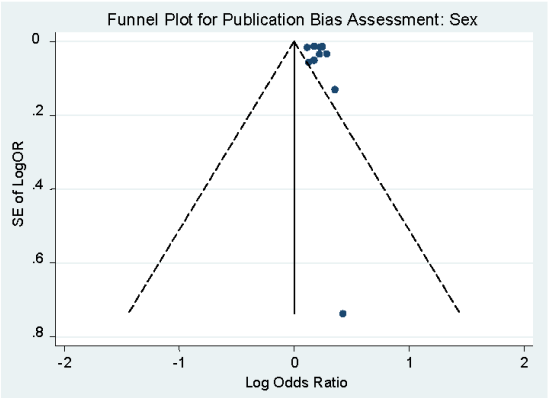
9 ((accident adj1 emergency) or ((assessment or emerg$ or trauma or triage) adj3 (department$ or room$ or service$ or unit$ or center$ or centre$ or ward$))).ti,ab.

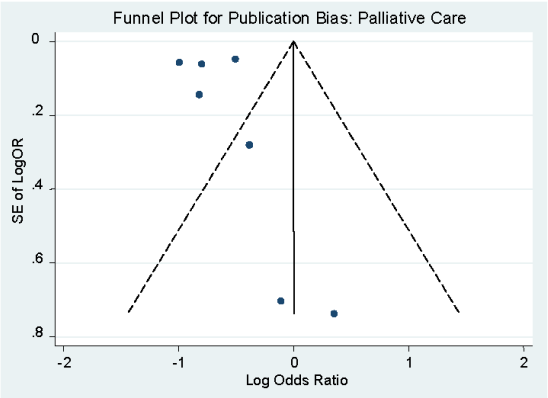
10 8 or 9

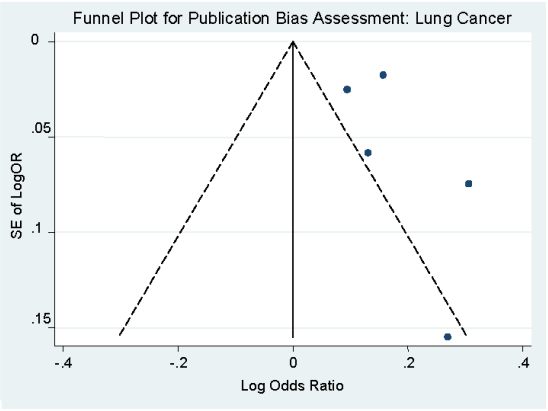
11 4 and 7 and 10

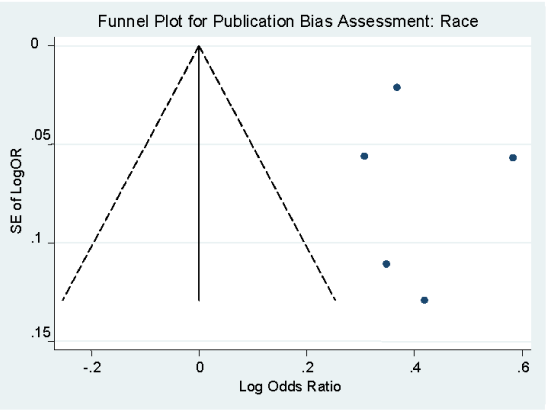
12 limit 11 to humans

3: Funnel plots for publication bias assessment









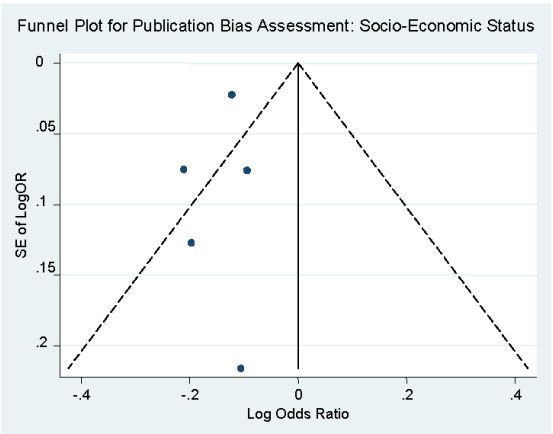


Table 1: Study Characteristics, Main Findings and Quality Assessment Score

First Author (Year), Setting	Population Description and Study Sample Size (n)	Outcome Description	Factors (reference group)	Key Findings	Quality Assessment Score*																
					Question/ objective sufficiently described? (Y=2, P=1, N=0)	Study design evident and appropriate (Y=2, P=1, N=0)	Method of subject/ comparison group selection OR source of information/ input variables described and appropriate? (Y=2, P=1, N=0, NA)	Subject (and comparison group, if applicable) characteristics sufficiently described? (Y=2, P=1, N=0)	If interventional and random allocation was possible, was it described? (Y=2, P=1, N=0, NA)	If interventional and blinding of investigators was possible, was it reported? (Y=2, P=1, N=0, NA)	If interventional and blinding of subjects was possible, was it reported? (Y=2, P=1, N=0, NA)	Outcome and (if applicable) exposure measure(s) well defined and robust to measurement/ misclassification bias? Means of assessment reported? (Y=2, P=1, N=0, NA)	Sample size appropriate? (Y=2, P=1, N=0, NA)	Analytic methods described/ justified and appropriate? (Y=2, P=1, N=0, NA)	Some estimate of variance is reported for the main results? (Y=2, P=1, N=0, NA)	Controlled for confounding? (Y=2, P=1, N=0, NA)	Results reported in sufficient detail? (Y=2, P=1, N=0)	Conclusions supported by the results? (Y=2, P=1, N=0)	**Total Sum of column**	**Total Possible Sum = 28 - (number of N/A *2)**	**Summary Score: total sum/ total possible sum**	**Overall Grading**
Almaawiy (2014), Canada	Population-based cohot of cancer patients in Ontario, Canada druing the calendar year 2006. Inclusion criteria: patients with a confirmed cancer diagnosis, older than 18 years, and with a valid provincial health insurance number. (n=9,467).	≥1 ED visit in last 2 weeks of life	Age (≥80 years) Gender (female) Rurality (urban) Income quintile (1 (lowest)) Comorbidity (Charlson score 0-6) Admission to homecare services (within 3-4 weeks of death) Type of cancer (lung) Average hours of nursing services per week (1 hour per week) Usual provider of care continuity score (low score)	**Reported AORs (95% CI)** 18-49 years: 1.21 (0.99-1.47), 50-59 years: 1.24 (1.06-1.46), 60-69 years: 1.14 (0.99-1.32), 70-79 years: 1.08 (0.95-1.23) Male: 1.19 (1.08-1.32) Rural: 1.62 (1.43-1.85) 2: 0.94 (0.82-1.08), 3: 0.99 (0.86-1.15), 4: 0.93(0.80-1.07), 5 (highest): 0.81 (0.70-0.94) Charlson score >6: 1.02 (0.93-1.13) Within 5-12 weeks of death: 0.73 (0.63-0.85), within 13-23 weeks of death: 0.55 (0.46-0.65), ≥24 weeks of death: 0.59 (0.50-0.70) Breast: 0.80 (0.66-0.98), colorectal: 0.70 (0.59-0.83), prostate: 0.67 (0.53-0.86), other: 0.88 (0.78-0.98) 2-3 hours: 0.98 (0.87-1.10), 4-5 hours: 0.79 (0.68-0.93), 6-7 hours: 0.70 (0.59-0.83), >7 hours: 0.49 (0.41-0.60), 0 hours: 0.96 (0.76-1.21) Zero family practitioner visits: 1.03 (0.85-1.25), medium score: 0.76 (0.67-0.86), high score: 0.59 (0.52-0.66)	2	2	1	2	NA	NA	NA	2	2	1	2	1	1	2	**18**	**22**	**0.82**	**High**
Barbera (2006), Canada	All patients who died of cancer in Ontario, Canada, during 2001, identified by the Ontario Cancer Registry. (n=21,323).	≥1 ED visit in last 2 weeks of life	Palliative care service (no) Age (<50 years) Gender (male) Rurality (urban) Income quintile (5 (highest)) Comorbidity (low) Homecare (no homecare) House call within 2 weeks of death (no) Type of cancer (lung)	**Reported AORs (95% CI)** Yes: 0.60 (0.55 -0.66) 50-69 years: 1.01 (0.89-1.16), ≥70 years: 0.93 (0.82-1.06) Female: 0.75 (0.70-0.80) Rural: 1.12 (1.02-1.22) 1 (lowest): 1.22 (1.10-1.35), 2: 1.16 (1.05-1.29), 3: 1.18 (1.06-1.31), 4: 1.08 (0.97-1.21) High: 1.10 (1.02-1.19) Home care within 6 months of death: 0.92 (0.86-0.99) Yes: 0.76 (0.70-0.82) Breast: 0.98 (0.86-1.13), CNS: 0.40 (0.31-0.52), colorectal: 0.84 (0.74-0.95), other GU/ gynae: 0.76 (0.66-0.88), head and neck: 0.83 (0.68-1.02), lymphoma/ leukemia: 0.89 (0.79-0.99), melanoma/ sarcoma: 0.71 (0.56-0.91), metastases: 1.06 (0.93-1.20), other: 0.76 (0.56-1.03), other GI: 0.88 (0.80-0.97), ovary: 0.93 (0.66-0.89), prostate: 0.77 (0.86-0.99)	2	2	2	2	NA	NA	NA	2	2	1	2	2	1	2	**20**	**22**	**0.91**	**High**
Barbera (2010), Canada	Population-based, retrospective cohort study of women who died of ovarian (ICD9 183), uterine (ICD9 179, 182) or cervical (ICD9 180) cancer in 2003 or 2004 in Ontario, Canada, as indicated by the death certificate. (n=2,040).	≥1 ED visit in last 2 weeks of life	Study reports *"Overall, older women were less likely to visit the ED (p=0.0013), most notably in uterine cancer patients. There was no statistically significant variation based on neighbourhood income quintile or region" (Barbera 2010, page 198)*		2	2	2	1	NA	NA	NA	2	1	1	0	1	1	2	**15**	**22**	**0.68**	**Medium**
Barbera (2010), Canada	All patients who died of cancer in Ontario, Canada, between 2002 and 2005, identified by the Ontario Cancer Registry. (n=91,561).	≥1 ED visit in last 2 weeks of life	Gender (male) Type of cancer (lung)	**Unadjusted ORs (95% CI) calculated from patient level data** Female: 0.78 (0.76-0.81) Breast: 0.71 (0.69-0.73), CNS 0.38: (0.37-0.39), colorectal: 0.64 (0.63-0.66), othe GU/ gynae: 0.64 (0.62-0.66), head and neck: 0.75 (0.73-0.77), lymphoma/ leukemia: 0.91 (0.88-0.93), melanoma/ sarcoma: 0.73 (0.71-0.75), metastases: 0.90 (0.88-0.93), other: 0.74 (0.72-0.76), other GI: 0.79 (0.77-0.81), ovary: 0.63 (0.61-0.64), prostate: 0.72 (0.70-0.74), non-melanoma skin: 0.49 (0.48-0.51)	2	2	2	2	NA	NA	NA	2	2	1	2	NA	2	2	**19**	**20**	**0.95**	**High**
Bergman (2011), USA	Men, aged ≥66 years, who died of prostate cancer between 1992 and 2005. (n=14,521).	>1 ED visit in last 30 days of life	Palliative care service (no)	**Reported AORs (95% CI)** Yes: 0.45 (0.40-0.51)	2	1	2	2	NA	NA	NA	2	2	2	2	2	2	2	**21**	**22**	**0.95**	**High**
Cowall (2012), USA	Random sample of all deaths from cancer, between 2004 and 2008, for persons who lived in Wiconmico County, Maryland. (n=390).	>1 ED visit in last month of life	Palliative care service (no) Gender (female)	**Unadjusted ORs (95% CI) calculated from patient level data** Yes: 1.42 (1.39-1.46) Male: 1.53 (1.49-1.58)	2	2	2	1	NA	NA	NA	1	2	2	2	1	1	2	**18**	**22**	**0.82**	**High**
	Adult (≥18 years) patients with			**Unadjusted ORs (95% CI) calculated from patient level data**	2	2	2	2	1	NA	NA	2	1	1	2	1	1	2	**19**	**24**	**0.79**	**High**

Daly (2013), USA	newly diagnosed with stage III or IV lung, gastrointestinal, or gynecologic cancer, and with an Eastern Cooperative Oncology Group performance status ≤3. (n=610).	>1 ED visit in last 30 days of life	Support and care coordination by an interdisciplinary cancer support team (no access to support team)	Access to support team: 0.91 (0.88-0.93)																
Earle (2004), USA	Patients aged ≥65 years, who died within one year of diagnosis from lung, breast, colorectal or other gastronintestinal cancer, between 1993 and 1996. (n=28,777).	>1 ED visit in last month of life	Age Gender (female) Rurality (rural) Type of cancer (lung) Race (White) Ethnicity (Non-Hispanic)	**Unadjusted ORs (95% CI)** OR for each increasing year of life: 0.99 (0.99-1.00) Male: 1.25 (1.17-1.34) Urban: 0.95 (0.83-1.09) Breast: 0.99 (0.84-1.15), colorectal: 0.81 (0.75-0.88), other GI: 0.93 (0.83-1.05) Black: 1.36 (1.22-1.52), Other: 0.99 (0.82-1.19) Hispanic: 1.32 (1.13-1.53)	2	2	2	2	NA	NA	NA	2	2	2	2	1	2	2	**21**	**22**	**0.95**	**High**
Geraci (2006), USA	Retrospective review of a random sample of cancer patients who visited the ED at a comprehensive cancer centre in January 2000. (n=396).	≥1 ED visit in last 2 weeks of life	Paper reports that the finding of cancer disease progression is associated with an risk of death within 14 days of ED visit.		2	2	2	2	NA	NA	NA	1	1	2	2	2	1	2	**19**	**22**	**0.86**	**High**
Gonsalves (2011), USA	Retrospective chart review comparing the last 100 patients who died with active cancer in 2002 with the last 100 patients who died in 2008. (n=200).	>1 ED visit in last 30 days of life	Palliative care service (no) Timing of referral to, or assessment by PC service, prior to death (>2 weeks)	**Unadjusted ORs (95% CI) calculated from patient level data** Yes: 0.90 (0.87-0.93) Referral to, or assessment by PC <2 weeks prior to death: 9.84 (9.58-10.12).	2	2	1	2	NA	NA	NA	2	1	2	1	1	2	2	**18**	**22**	**0.82**	**High**
Ho (2011), Canada	Population-based, retrospective study of all patients, aged ≥20 years, who died from any type of cancer in Ontario, Canada, in 1993 or 1994, and had a valid provincial health insurance number. (n=227,161).	>1 ED visit in last 30 days of life	Gender (female) Rurality (urban) Income quintile (5 (highest)) Comorbidity Type of cancer (other)	**Unadjusted ORs (95% CI)** Male: 1.26 (1.22-1.30) Rural: 1.44 (1.38-1.49) 1 (lowest): 1.13 (1.08-1.18), 2: 1.07 (1.03-1.12), 3: 1.10 (1.06-1.15), 4: 1.07 (1.02-1.12) Per point on Charlson score: 1.18 (1.17-1.20) Lung: 1.17 (1.13-1.21), breast: 1.07 (1.01-1.13), colorectal: 0.94 (0.90-0.99), haematological: 1.28 (1.22-1.34), prostate: 1.05 (0.99-1.12)	2	2	2	2	NA	NA	NA	2	2	2	2	2	2	2	**22**	**22**	**1.00**	**High**
Jang (2013), Canada	Population-based, retrospective study of patients who died from advanced pancreatic cancer between 2005 and 2010 in Ontario, Canada. (n=5,381).	>1 ED visit in last 30 days of life	Palliative care service (no)	**Reported AORs (95% CI)** Yes: 0.44 (0.33-0.58)	2	2	1	0	NA	NA	NA	1	2	1	1	1	1	1	**13**	**22**	**0.59**	**Low**
Keam (2008), Republic of Korea	Patients diagnosed with metastatic cancer, and received palliative chemotherapy at Seoul National University Hospital in 2002. (n=298).	>1 ED visit in last month of life	Timing, with relation to death, of discontinuation of chemotherapy (discontinuation of chemotheapry ≥3 months before death)	**Unadjusted ORs (95% CI) calculated from patient level data** Discontinuation of chemotherapy within 2 months of death: 4.14 (4.03-4.26)	1	2	2	1	NA	NA	NA	2	2	1	2	0	1	2	**16**	**22**	**0.73**	**High**
Keating (2010), USA	A sample of men, diagnosed with stage IV lung or colorectal cancer in 2001-2002, and who died before 2006, treated in either the Veterans Health Administration (VHA) or under fee-for-service Medicare (FFS). (n=5,826).	>1 ED visit in last 30 days of life	Race (non-Hispanic White) Healthcare system (FFS)	**Unadjusted ORs (95% CI) calculated from patient level data** Black (VHA sample only): 1.43 (1.39-1.47), Black (FFS sample only): 1.06 (1.03-1.09) VHA: 0.88 (0.85-0.90)	2	1	2	2	NA	NA	NA	2	2	2	2	2	2	2	**21**	**22**	**0.95**	**High**
Leak (2012), USA	Population-based analysis of all cancer patients who died during an ED visit in North Carolina during 2008. (n=283).	Died in the ED	Males accounted for 62.5% of cancer-related ED deaths. The average age of those who died in the ED was 66 years. 36.7% of cancer-related ED deaths were patients with a diagnosis of lung cancer, and this was significantly higher than other cancers - 2.1% breast cancer, 2.8% prostate cancer and 7.1% colorectal cancer. The most common chief complaints of those who died in the ED were respiratory (17.6%), gastrointestinal (16.2%) and neurological (14.1%).		2	2	2	2	NA	NA	NA	1	1	1	1	0	1	2	**15**	**22**	**0.68**	**Medium**
Loggers (2012), USA	Integrated health systems enrollees who died from cancer between 2000 and 2008. (n=8,402).	>1 ED visit in last 30 days of life	Age (<65 years)	**Unadjusted ORs (95% CI) calculated from patient level data** ≥65 years: 1.01 (0.98-1.04)	1	1	2	0	NA	NA	NA	2	2	0	0	NA	0	0	**8**	**20**	**0.40**	**Low**
Lopez-Acevedo (2013), USA	Retrospective study of women who died of ovarian cancer diagnosed between 1999 and 2008. (n=220).	>1 ED visit in last 30 days of life	Timing, with relation to death, of end of life care discussion (EOLC discussion <30 days before death)	**Unadjusted ORs (95% CI) calculated from patient level data** EOLC discussion ≥30 days before death: 0.14 (0.14-0.15)	2	2	2	2	NA	NA	NA	2	1	2	2	2	2	2	**21**	**22**	**0.95**	**High**
Mack (2012), USA	Patients with stage IV lung or colorectal cancer who died during a 15-month study period, but survived at least 1 month following diagnosis. (n=1,231).	>1 ED visit in last 30 days of life	Timing, with relation to death, of end of life care discussion (EOLC discussion <30 days before death)	**Unadjusted ORs (95% CI) calculated from patient level data** EOLC discussion ≥30 days before death: 0.37 (0.36-0.38)	2	2	2	2	NA	NA	NA	2	1	2	2	2	2	2	**21**	**22**	**0.95**	**High**
Maddison (2012), Canada	All adults (≥20 years), who died of colorectal cancer in Nova Scotia, Canada, between 2001 and 2008.	≥1 ED visit in last 30 days of life	Palliative care service (no) Timing, with relation to death, of palliative care service (PC service <60 days prior to death) Age (<65 years) Gender (male) Rurality (rural)	**Reported AORs (95% CI)** Yes: 0.68 (0.40-1.20) PC service ≥60 days prior to death: 0.65 (0.40-1.10) 65-74 years: 0.89 (0.60-1.30), 75-84 years: 0.70 (0.50-1.10), ≥85 years: 0.60 (0.30-1.00) Female: 0.70 (0.60-1.00) Urban: 3.18 (2.00-5.10)	2	1	2	2	NA	NA	NA	2	2	2	2	2	1	2	**20**	**22**	**0.91**	**High**

Canada	(n=1,201).		Income Band (<30k per annum)	30-44,999k per annum: 0.79 (0.60-1.20), ≥45k per annum: 0.90 (0.60-1.40)																
			Number of comorbidities (0 comorbidities)	1: 0.71 (0.50-1.10), ≥2: 0.94 (0.60-1.40)																
			Stage of Disease (IV)	III: 1.15 (0.80-1.70), II: 0.71 (0.40-1.20), I: 1.11 (0.80-1.40), Unknown: 0.54 (0.20-1.2)																
			Long-term care resident (no)	Yes: 0.44 (0.20-1.20)																
Miesfeldt (2012), USA	Retrospective cohort analysis of a 20% sample of fee-for-service Medicare patients dying from poor-prognosis cancers between 2003 and 2007. (n=235,821).	>1 ED visit in last 30 days of life		**Unadjusted ORs (95% CI) calculated from patient level data**	1	2	2	2	NA	NA	NA	2	2	2	2	2	2	2	**21**	**22**	**0.95**	**High**
			Age (<75 years)	≥75 years: 0.88 (0.86-0.90)																
			Gender (female)	Male: 1.19 (1.16-1.22)																
			Race (non-Black)	Black: 1.44 (1.41-1.49)																
Murray (2011), USA	Retrospective cohort analysis of a 20% sample of fee-for-service Medicare patients dying from poor-prognosis cancers between 2003 and 2007. (n=235,821).	>1 ED visit in last 30 days of life		**Unadjusted ORs (95% CI) calculated from patient level data**	1	1	1	1	NA	NA	NA	2	2	1	0	1	0	0	**10**	**22**	**0.45**	**Low**
			Principle healthcare provider in the last month of life (primary care physician only)	Oncology specialist: 0.42 (0.41-0.44), primary care physician and oncology specialist: 1.33 (1.29-1.37)																
Nevadunsky (2014), USA	Retrospective review of 100 consecutive patients who died from a primary gynecological malignancy. (n=100).	>1 ED visit in last 30 days of life		**Unadjusted ORs (95% CI) calculated from patient level data**	2	2	1	1	NA	NA	NA	2	1	2	2	1	2	2	**18**	**22**	**0.82**	**High**
			Timing of referral to, or assessment by PC service, prior to death (<30 days prior to death)	Referral or assessment by PC ≥ 30 days prior to death: 19.3 (18.7-19.8)																
Saito 2011, USA	Patients aged ≥65 years, who died of advanced non-small-cell lung cancer from 1991 to 1999. (n=7,879).	>1 ED visit in last month of life		**Unadjusted ORs (95% CI) calculated from patient level data**	2	2	2	2	NA	NA	NA	2	1	1	2	2	2	2	**20**	**22**	**0.91**	**High**
			Palliative care service (no)	Yes: 0.37 (0.36-0.38)																
			Timing of referral to, or assessment by PC service, prior to death (>3 days prior to death)	Referral of assessment by PC ≤3 days prior to death: 3.86 (3.76-3.97)																
Seow (2010), Canada	Retrospective study of decedents admitted to end-of-life homecare in Ontario, Canada. (n=9018).	≥1 ED visit in last 2 weeks of life		**Reported AORs (95% CI)**	2	2	2	2	NA	NA	NA	2	2	2	2	2	2	2	**22**	**22**	**1.00**	**High**
			Age (18-79 years)	≥80 years: 0.71 (0.61-0.82)																
			Gender (male)	Female: 0.88 (0.79-0.99)																
			Rurality (urban)	Rural: 1.32 (1.10-1.58)																
			Income band (lowest)	Highest: 0.91 (0.78-1.05)																
			Comorbidity (Charlson score 0-5)	Charlson score ≥6: 0.96 (0.85-1.08)																
			Homecare services (admission to homecare within 3-4 week of death)	Admission with 5-12 weeks: 0.80 (0.68-0.93), within 13-23 weeks: 0.74 (0.61-0.88), admission ≥24 weeks: 0.71 (0.59-0.85)																
			Average hours per week of personal support and homemaking services (average of 1 hour per week)	2-3 hrs/wk: 1.16 (0.92-1.47), 4-5 hrs/wk: 0.77 (0.57-1.05), 6-7 hrs/wk: 1.04 (0.75-1.44), >7 hrs/wk: 0.73 (0.56-0.94), 0 hrs/wk: 1.29 (1.08-1.55)																
			Nursing services (average of 1 hour per week)	2-3 hrs/wk: 0.91 (0.79-1.06), 4-5 hrs/wk: 0.85 (0.70-1.06), 6-7 hrs/wk: 0.63 (0.48-0.82), >7 hrs/wk: 0.51 (0.37-0.70), 0 hrs/wk: 0.73 (0.60-0.90)																
Serra Prat (2001), Spain	Patients undergoing palliative treatment who died from cancer in Mataro, Spain, in 1998. (n=155).	≥1 ED visit in last month of life		**Unadjusted ORs (95% CI) calculated from patient level data**	2	2	2	0	NA	NA	NA	2	1	1	2	0	1	1	**14**	**22**	**0.64**	**Medium**
			Additional palliative homecare support (standard care, i.e. No additional support team care)	Additional homecare support: 0.16 (0.15-0.16)																
Smith (2009), USA	Fee-for-service Medicare beneficiaries aged ≥65 years with advanced stage lung, colorectal, breast or prostate cancer. (n=40,960).	>1 ED visit in last month of life		**Reported AORs (95% CI)**	2	1	2	2	NA	NA	NA	2	2	2	2	2	0	2	**19**	**22**	**0.86**	**High**
			Race (non-Hispanic White)	non-Hispanic Black: 1.60 (1.40-1.83)																
Tang (2009), Taiwan	Patients who died from cancer between 2001 to 2006 in Taiwan. (n=210,976).	>1 ED visit in last month of life		**Unadjusted ORs (95% CI)**	2	2	2	1	NA	NA	NA	2	2	1	2	1	2	2	**19**	**22**	**0.86**	**High**
			Age (<65 years)	65-74 years: 0.91 (0.88-0.94), 75-84 years: 0.83 (0.80-0.87), ≥85 years: 0.80 (0.75-0.86)																
			Gender (male)	Female: 0.89 (0.86-0.92)																
			Marital status (married)	Single: 0.87 (0.85-0.92), divorced/ separated: 0.99 (0.94-1.04), widowed: 1.01 (0.98-1.04)																
			Number of comorbidities (0 or 1 comorbidity)	2: 1.10 (1.06-1.14), 3: 1.13 (1.09-1.18), ≥4: 1.22 (1.17-1.27)																
			Type of cancer (lung)	Gastric: 0.96 (0.90-1.02), pancreatic/ bile duct: 0.99 (0.92-1.06), liver: 1.33 (1.26-1.41), oesophageal: 1.11 (1.04-1.19), breast: 0.93 (0.83-1.04), colorectal: 0.87 (0.82-0.92), head and neck: 1.13 (1.06-1.19), haematological: 1.10 (1.02-1.19), other: 0.91 (0.87-0.96), prostate: 1.08 (0.99-1.18)																
			Principle healthcare provider in the last month of life (oncology specialist)	Non-oncology healthcare provider: 1.14 (1.04-1.24)																
Temel (2008), USA	Patients within 8 weeks of diagnosis of stage IIIb (with effusions) or IV non-small cell lung cancer. (n=40).	≥1 ED visit in last 30 days of life	Descriptive pilot study examining markers of aggressive end of life care for patients with advanced non-small cell lung cancer. Exploratory bivariate analyses found no associated between patient characteristics, mood symptoms, or quality of life indicators and ED visits towards the end of life.		1	2	2	1	NA	NA	NA	2	0	1	2	1	1	2	**15**	**22**	**0.68**	**Medium**
	Patients with pathologically			**Unadjusted ORs (95% CI)**	2	2	2	2	2	NA	NA	2	1	2	2	2	2	2	**23**	**24**	**0.96**	**High**

Temel (2010), USA	confirmed, newly diagnosed, metastatic non-small cell lung cancer, and an Eastern Cooperative Oncology Group performance status of 0, 1 or 2. (n=151).	≥1 ED visit in last 30 days of life	Early PC integrated with standard oncology care (standard oncological care alone)	Early PC integrated with standard oncological care: 0.66 (0.65-0.68)																	
Warren (2011), Canada and USA	Patients, ≥65 years, who died from non-small cell lung cancer, between 1999 and 2003. (n=21,633).	≥1 ED visit in last 30 days of life	Healthcare system in varying countries (USA)	**Unadjusted ORs (95% CI)** Canada: 1.64 (1.60-1.69)	1	2	2	2	NA	NA	NA	2	2	2	2	2	2	2	**21**	**22**	**0.95**	**High**

2.4 Summary of Background and Rationale for Study

Despite advances in prevention, early detection and treatment, cancer remains one of the commonest causes of morbidity and mortality worldwide (1). With population growth and ageing, the number of deaths from cancer is anticipated to rise (10), and the importance of providing high-quality end-of-life care, in accordance with patients' needs and preferences, is increasingly recognised (12).

Towards the end-of-life, people with cancer wish to be comfortable, be treated respectfully and holistically by healthcare professionals they trust, and have an opportunity to achieve a sense of completion (13-16). Most (64-84%) prefer to be cared for and die at home, and to avoid overly 'intensive' or 'aggressive' care, which can be defined as care that focuses mostly or exclusively on disease-modifying treatments at the expense of good symptom management and/or advance care planning (14-18). One validated marker of overly aggressive end-of-life cancer care is the proportion of patients with multiple (≥2) ED visits during their last month of life. ED visits are associated with an increased risk of poor patient and caregiver outcomes, such as prolonged pain, an overall dissatisfaction with care, and an increased risk of psychiatric illness in bereaved relatives (61-63). From a societal perspective, ED utilisation is of particular relevance due to the high costs associated with providing such care and ongoing capacity concerns for many EDs across developed countries (36, 37, 39). Yet despite the above, end-of-life ED visits by people with cancer are increasing over time (50, 51). This situation not only fails many patients and their caregivers in the delivery of high-quality end-of-life care, but is unsustainable given the predicted increases in cancer prevalence (11, 64). Reducing ED attendance must not be at the expense of promoting appropriate attendance for those in need; however, targeting patients whose attendance may be classed as avoidable and providing alternative, more suitable care pathways is desirable.

At present there is limited understanding of cancer patients' end-of-life ED use. Most of the existing research has focused on quantifying attendance and/or investigating factors associated with an increased risk of multiple ED visits towards the end-of-life (65, 66). Whilst these studies have identified various socio-demographic, clinical and environmental risk factors, important gaps in the literature have also been highlighted. Data from the UK, with its unique publicly funded model of healthcare delivery, is absent. There is also limited and/or conflicting results for several factors, such as patients' level of co-morbidity, cancer diagnosis and rurality of usual place of residence. Qualitative research exploring why advanced cancer patients decide to attend the ED is limited (67, 68). Furthermore, an integrated summary of the factors associated with end-of-life ED visits (quantitative research) and the decision-making processes of advanced cancer patients to seek ED care (qualitative research) is lacking.

2.5 Aim and Objectives

2.5.1 Aim

To understand variation in cancer patients' end-of-life (last month) ED use in order to support the development of future initiatives aimed at reducing high attendance and improving equity of access to end-of-life healthcare services.

2.5.2 Objectives

1) To describe ED use by patients with cancer towards the end-of-life and determine the relationship between number of ED visits and socio-demographic, clinical and environmental factors.
2) To explore advanced cancer patients' and their caregivers' decisions to seek ED care, and understand the issues that influence the decision-making process.
3) To integrate the findings from objectives 1 and 2 in order to develop a conceptual model of advanced cancer patients' ED use, from which key elements to inform future service development can be identified.

Chapter 3 - Study Design and Overview of Methods

In order to address the research aim and objectives a mixed methods study with a concurrent triangulation design was planned (Figure 3.1) (69). These comprised:

1) Secondary analysis of pooled data from two mortality follow-back studies: the QUALYCARE study (UK Clinical Research Network (CRN) ID 7041) (70) and the International Access, Rights and Empowerment (IARE) study (UK CRN ID 11879) (71).
2) A population-based retrospective cohort study using linked patient-level data from the Office for National Statistics (ONS) and Hospital Episode Statistics (HES): dataset supplied by NHS Digital (72).
3) A qualitative interview study with data collected via semi-structured patient and caregiver interviews, and a review of patients' healthcare records.

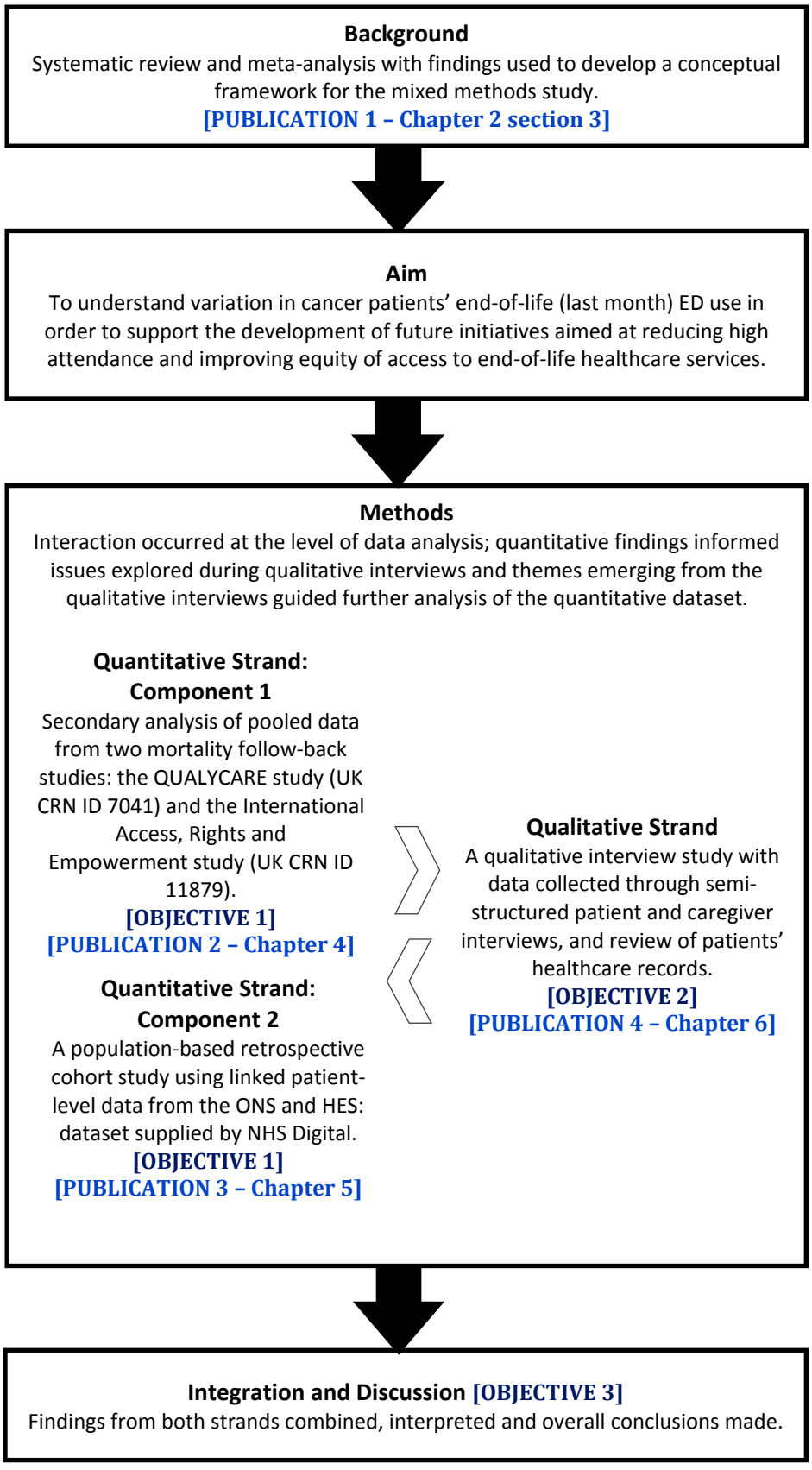


Figure 3.1: Overview of study design and relationship to objectives

3.1 Mixed Methods Research

3.1.1 Definition

Creswell (69) defines mixed methods research as 'an approach to inquiry that combines or associates both qualitative and quantitative forms. It involves philosophical assumptions, the use of qualitative and quantitative approaches, and the mixing of both approaches in a study' (p.4). By utilising the strengths of both quantitative and qualitative approaches, mixed methods research is especially useful when investigating complex behavioural and/or clinical phenomena, such as ED use, where a single method approach would be unlikely to capture the totality of the study subject (73, 74).

3.1.2 The Choice of Mixed Methods

For this study the decision to use mixed methods was largely determined by the complexity of the research topic and its overall aim and objectives. Quantitative methods were used to describe and investigate cancer patients' end-of-life ED use according to multiple independent factors (objective 1). To understand how and why these factors influenced cancer patients' ED use, qualitative methods were adopted, allowing an exploration of cancer patients' thought processes and decision-making (objective 2). When combined, the quantitative and qualitative findings provided different but complementary data concerning cancer patients' end-of-life ED use. Integration ultimately enhanced the understanding of the study subject and resulted in knowledge that was greater than the sum of the individual parts (objective 3) (74).

3.1.3 Theoretical Considerations when using Mixed Methods

The use of mixed methods in research has increased over recent years and now offers a recognised approach for investigating diverse health and social care issues. Yet despite growing acceptability philosophical debates remain, mostly regarding how to combine and interpret

knowledge gained from research methods associated with very different and classically conflicting research paradigms. Quantitative research is traditionally associated with positivism. A positivist believes in a single reality which can be measured and known, and 'adheres to the view that only "factual" knowledge gained through observation (the senses), including measurement, is trustworthy' (75). In comparison, qualitative research is most commonly associated with interpretivism or constructivism. Interpretivists do not believe in a single reality or truth, rather they adopt a more flexible approach to research, believing that reality is created by individuals and therefore requires interpretation (69).

The research philosophy in which the present study was conducted was one of realism. Realism acknowledges the existence of an objective reality (one that is independent of human construction and can be counted), however it also accepts that knowledge and understanding of this 'real' world is derived from one's personal thoughts and experiences (76). Whilst realism rejects the idea of multiple realities, it is compatible with the idea that there are different and valid perspectives of a single reality, and consequently reasons that an approach which gains multiple vantages ought to ultimately result in more complete knowledge and understanding (76).

3.2 Methodological Challenges and Considerations

The following section of this thesis describes some of the methodological challenges encountered whilst undertaking this research. The ethical approvals required for each study component are also presented. A more detailed description of the research methods can be found in each study component's corresponding publication (Chapters 4 to 6).

3.2.1 Quantitative Strand

Whilst the final quantitative strand of this study consisted of two components, the initial design proposed included only one, a population-based retrospective cohort study. This preliminary design was revised after encountering considerable challenges in acquiring the requested dataset from NHS Digital (formerly the Health and Social Care Information Centre (HSCIC)). The study design revisions resulted in an additional analysis being conducted prior to the retrospective cohort study. This additional secondary analysis used pooled data from two mortality follow-back surveys (Figure 3.1).

3.2.2 NHS Digital Data Acquisition Challenges

Sponsored by the Department of Health, UK, NHS Digital provide commissioners, analysts and healthcare staff with access to a wide range of data products, information services and systems (77). Their products include HES, a data repository of patient-level activity occurring across NHS hospitals in England. They also offer a linkage service between their own data products and those of other national bodies, such as the ONS. Under usual circumstances, data applications to NHS Digital take up to 60 days to be processed (78).

In September 2013, an application for linked ONS HES data was submitted to NHS Digital; however, shortly after this application, NHS Digital commenced an internal review of all their data release policies in response to an NHS patient data audit which raised concerns about their use of public information (79). Amongst the audit findings was evidence of 'lapses in the strict arrangements that were supposed to be in place to ensure that people's personal data would never be used improperly' (80). Whilst an internal review took place and changes to NHS Digital's data handling processes were implemented, lengthy delays were experienced by all data applicants. Copies of the original data application form and email correspondence with NHS Digital can be found in Appendix A.

The dataset requested from NHS Digital was finally received in December 2014, some 15 months after the original application was submitted. Analysis was completed according to the original protocol and is presented in the form of a published paper in Chapter 5. However, due to the extensive delays and uncertainty regarding when the data would become available, in April 2014 it was elected to explore alternative datasets also suitable of addressing the study's quantitative objective (objective 1). After considering different options it was decided to pool data from two recently conducted mortality follow-back surveys: the QUALYCARE study (UK CRN ID 7041) (70) and the IARE study (UK CRN ID 11879) (71). In both studies patients' bereaved relatives/significant others were surveyed via a postal questionnaire regarding the care received by their family member/friend during the last three months of life. The questionnaire used was initially developed for the QUALYCARE study and then later adapted for use by the IARE study. Both versions included the same two questions concerning ED attendance: 'We would like to know about the care your relative or friend received during the last 3 months before he/she died. Did he/she visit an Accident & Emergency (A&E) department? & How many times?'.

3.2.3 Strengths and Limitations of the Additional Quantitative Analysis

During planning of the additional analysis three main benefits were recognised. Firstly, the mortality follow-back surveys contained several community healthcare service variables, such as GP home visits, district nursing and contact with palliative care services, which were not available from NHS Digital. Secondly, the pooled dataset was considerably smaller than the dataset requested from NHS Digital (n=681 versus n=124,030 and 103 variables versus 332). Cleaning of the dataset was therefore quicker than anticipated and meant that in addition to investigating the relationship between multiple factors and end-of-life ED visits, the relationship with other recognised indicators of overly aggressive end-of-life cancer care, for example place of death, could also be explored. Lastly, the additional analysis provided me with an opportunity

to improve my statistical analysis skills and use of the statistical data package Stata/IC 13 (STATA, College Station, Tx).

It was also recognised that the additional analysis would have limitations. Both mortality follow-back surveys asked about cancer patients' ED use in the last three months of life – an outcome which was different to the planned analysis exploring cancer patients' ED use in the last month of life. This latter time period was specifically chosen as the prevalence of ED visits during the last month of life is a recognised and validated indicator of overly aggressive end-of-life cancer care, for which benchmarking data is also available (26). It was acknowledged that this is not the case for ED visits in the last three months of life. The study settings and populations also differed; whilst the NHS Digital dataset was population-based (comprising all adults who died from cancer in England during a one year period), the mortality follow-back surveys consisted of data from a sample of patients who had died from cancer across four London boroughs, therefore limiting generalisability. Despite these limitations it was felt that the additional knowledge gained from the mortality follow-back surveys was important and relevant to understanding cancer patients' end-of-life ED use. The analysis was therefore included with the population-based cohort study in the presentation of the final research findings.

3.3 Ethics

3.3.1 Quantitative Strand: Component 1

Ethical approval had been granted for both the original QUALYCARE and IARE studies. Prior to conducting any further analysis, the protocols for both studies were reviewed to determine whether the additional analysis proposed fell within the scope of the original projects' aims and objectives. After this was confirmed, all National Research Ethics Committee data requirements, such as confidentiality agreements, were fulfilled (Appendix B).

3.3.2 Quantitative Strand: Component 2

For the population-based retrospective cohort study, approval was received from NHS Digital who also extracted and provided the bespoke data-linked dataset (reference number: NIC-223311-Z0B8Q). As all data was pseudonymised, and therefore non-identifiable, no further ethical approvals were required to complete the analysis (Appendix C).

Quantitative Data Management

Data was managed in a strictly confidential manner and in accordance with all relevant policy documents for handling sensitive and/or personal information. This included data being encrypted and stored on a secure password-protected system, only accessible by those individuals named in the data agreement contracts. Information shared with third parties, such as data submitted to journals for publication, had all identifying details removed. Low counts ($n<10$) were also suppressed in-line with good data handling practice and requirements from NHS Digital regarding data reporting.

3.3.3 Qualitative Strand

Ethical approval for the qualitative interview study was received from the National Research Ethics Service Committee South Central – Berkshire (research ethics committee reference 14/SC/1207) and the Research and Development Office at King's College Hospital (reference KCH14-171). Copies of the research and ethics committee application and corresponding approval documents can be found in Appendix D.

Ethical Considerations

There is a substantial and growing body of evidence, including two systematic reviews, of the benefits experienced by individuals with life-limiting conditions from participating in research (81, 82). However, despite these benefits, conducting research in vulnerable populations, such as those with terminal illnesses, requires particular thought and consideration. In-depth

research interviews may uncover new or inadequately managed health and/or psycho-social concerns. Some participants may also find elements of the interview process distressing. Prior to the qualitative interview study commencing these issues were carefully considered and plans were made to reduce potential sources of distress. To help them feel as comfortable as possible, participants were offered a choice of interviews settings, including their own home. A distress protocol was also developed based on those successfully used by previous qualitative researchers in the Division of Palliative Care, Policy & Rehabilitation, King's College London (Appendix E). During the interviews participants were monitored for signs of distress, breaks were incorporated and interviews ended early if needed.

As well as the impact of qualitative research on study participants, the interaction between researchers and the study process also requires consideration. Qualitative inquiry requires researchers to closely engage with both their study participants and the research process. Consequently, it is acknowledged that when conducting qualitative studies researchers' personal experiences and/or biases cannot be completely without influence. To improve the credibility of qualitative findings researchers should make attempts to minimise any potential biases. They should also recognise and clarify for other readers elements about themselves that may have influenced their participation in the research process, for example their occupation, experience and/or training (83). For these reasons, I offer the following short autobiography and personal reflections on how my individual characteristics may have influenced the research process and/or study findings.

Autobiography

I was born in Cardiff, Wales, in 1981, to an American mother and English father; I am the middle daughter of three children. Following my A-Levels I went to London to study medicine at Guy's, King's and St Thomas' School of Medicine and Biomedical Sciences. I graduated in 2005 and

spent the next four years working as a junior doctor across London and the South East. During this time I completed my Membership of the Royal College of Physicians (MRCP) and also made the decision to pursue a career in palliative care. I started specialist palliative care training in October 2009, with my first two years spent working in rural hospices in England: Pilgrim's Hospice, Canterbury, and Hospice in the Weald, Tunbridge Wells. I then made the decision to take a 12-month break from formal registrar training to volunteer as a Palliative Care Clinical Research Fellow at Mulago Hospital, Kampala, Uganda. Whilst working in Uganda I had the opportunity to assist with a number of different research projects, including a qualitative evaluation of a palliative care pilot project in the Lake Zone of Tanzania (84). This experience, and the fulfilment I found using my clinical knowledge in a research capacity, made me want to continue working in an academic setting. Towards the end of my year in Uganda I began looking for further opportunities to develop my research knowledge and skills, including the possibility of conducting my own supervised research project through a PhD fellowship. These plans became reality in September 2012 when I proudly accepted the position of BuildCARE PhD Clinical Training Fellow at the Cicely Saunders Institute, Division of Palliative Care, Policy & Rehabilitation, King's College London.

Influence of Personal Characteristics on Research Process and Study Findings

Social, cultural and personal characteristics inevitably shape relationships, including those that develop as part of a research study. Rather than trying to prevent this from happening, researchers should recognise these situations and explore how they may be affecting the findings of the study. For this qualitative interview study, I explained to participants that I was working with the palliative care or acute oncology team at King's College Hospital to conduct a study about decisions to seek ED care. No further information about myself or the research team was offered; however, I replied honestly to any participants who asked me about my profession. I believe that my position as a doctor, as well as my age, gender and ethnicity, had some degree

of influence on the study conduct and its findings. As a doctor I was viewed by some participants as having knowledge and/or being in a position of power. As a consequence, social desirability may have influenced some of the answers given and/or impacted what information participants felt able to share. Characteristics, such as my age, gender and ethnicity, meant I established a rapport with some participants more easily than others. This mostly offered an advantage, allowing me to engage with participants and introduce difficult topics of conversation more easily. However, it also meant that there were times when I took for granted certain aspects of participants' narratives, believing there was a shared meaning and understanding.

Reflections on the Qualitative Interview Process

At the start of my PhD fellowship I had limited research experience. Despite additional training, the qualitative interview study involved a steep learning curve. After completing my first three interviews I spent time reviewing the transcripts and discussing their content with my PhD supervisors. I found that whilst these interviews had generated large volumes of data, the issues discussed were rather predictable and lacked the depth and richness of information required. There were times when I interrupted the participant and/or used leading questions. I also spent too much time clarifying small details in order to find the most accurate account of events, rather than focusing on the language used by participants and the way in which important issues were being described. As a palliative care registrar I have received training in advanced communication skills and have extensive experience of 'interviewing' patients through clinical history taking. This background provided me with relevant and transferable skills, including the ability to build a rapport with participants and engage in conversations about sensitive issues, such as death and dying. However, almost all these experiences have been in relation to clinical encounters where the interview style and purpose is very different. Doctor-patient interviews stem from a bio-medical model of health, where 'although the doctor may be willing to see the problem from the patient's perspective, the clinical task is to fit that problem into an appropriate

medical category in order to choose an appropriate form of management' (85, 86). Appreciating these fundamental differences helped me develop a more exploratory style of interviewing, and I began to realise the depth of information behind what I previously might have considered straight forward statements of fact. Following feedback, I learned to assume less and prompt more; I began asking fewer questions and instead focused on how participants described and interpreted their realities. Overall, the process was enlightening, and has made me a better qualitative researcher and more insightful palliative care physician.

3.4 Presentation of Results

The results of this study are presented in the form of three published papers. The first two publications address objective 1 and collectively represent the quantitative strand of this study. The third publication addresses objective 2 and represents the qualitative strand. Objective 3 is addressed in Chapter 7, when the quantitative and qualitative findings are integrated and overall conclusions made.

Chapter 4 - Factors Associated with Aggressive End of Life Cancer Care [PUBLICATION 2]

Support Care Cancer
DOI 10.1007/s00520-015-2885-4

ORIGINAL ARTICLE

Factors associated with aggressive end of life cancer care

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Received: 29 May 2015 / Accepted: 29 July 2015

Abstract
Background Many patients with cancer experience aggressive care towards the end of life (EOL) despite evidence of an association with poor outcomes such as prolonged pain and overall dissatisfaction with care.
Purpose To investigate socio-demographic, clinical and community health care service factors associated with aggressive EOL cancer care.
Methods An analysis of pooled data from two mortality follow-back surveys was performed. Aggressive EOL care was defined as greater than or equal to one of the following indicators occurring during the last 3 months of life: greater than or equal to two emergency department visits, ≥30 days in hospital and death in hospital.
Results Of the 681 included patients, 50.1 % were men and mean age at death was 75 years. The majority of patients (59.3 %, 95 % confidence interval (CI) 55.6–63.0 %) experienced at least one indicator of aggressive EOL care: 29.7 % experienced greater than or equal to two ED visits, 17.1 % spent ≥30 days in hospital and 37.9 % died in hospital. Patients with prostate or haematological cancer were more likely to experience aggressive EOL care (adjusted odds ratio (AOR) 4.36, 95 % CI 1.39–13.70, and 4.16, 95 % CI 1.38–12.47, respectively, reference group lung cancer). Patients who received greater than five general practitioner (GP) home visits (AOR 0.37, 95 % CI 0.17–0.82, reference group no GP visits) or had contact with district nursing (AOR 0.48, 95 % CI 0.28–0.83, reference group no contact) or contact with community palliative care services (AOR 0.27, 95 % CI 0.15–0.49, reference group no contact) were less likely to experience aggressive EOL care. No association was found between aggressive EOL care and patients' age, gender, marital, financial or health status.
Conclusions Community health care services, in particular contact with community palliative care, are associated with a significant reduction in the odds of cancer patients receiving aggressive EOL care. Expansion of such services may help address the current capacity crises faced by many acute health care systems.

Keywords Neoplasms · Palliative care · Terminal care · Community health services · Emergency service · Hospital · Hospital mortality

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Introduction

Towards the end of life (EOL), patients with cancer wish to be comfortable, be afforded dignity and privacy, and have the opportunity to achieve a sense of completion [1–4]. They also wish to avoid overly 'intensive' or 'aggressive' medical care which can be defined as care that focuses mostly or exclusively on disease-modifying treatments at the expense of good symptom management and/or advance care planning. In 2003, Earle and colleagues identified several markers of potentially overly aggressive EOL cancer care including multiple emergency department (ED) visits towards the EOL, a high number of days spent in hospital or intensive care towards the EOL, death in hospital and an underuse of hospice services [5]. Since then, several studies have further supported these findings with evidence of an association between aggressive EOL care and poor symptom control, reduced patient quality of life and an increased risk of psychiatric illness in

bereaved caregivers [6–8]. Furthermore, in a randomised controlled trial of early palliative care for patients with advanced non-small cell lung cancer, Temel and colleagues found that overly aggressive EOL care may even shorten survival [9].

From a societal perspective, it is important to consider the cost-effectiveness of any health care service delivered. In the USA >10 % of the total health care budget and as much as 30 % of the Medicare budget are spent on care for those in the last year of life [10, 11]. In the UK expenditure is similar with an estimated 20 % of the National Health Service budget spent on care for those in the last year of life [12]. For cancer patients, health care spending has been shown to increase substantially in the months prior to death, with the additional costs being mostly attributable to an increased use of acute health care services such as unplanned hospital admissions and ED visits [11, 13, 14].

Yet, despite these potentially negative outcomes for both individuals and society, EOL cancer care is becoming increasingly aggressive over time [15–19]. In a population-based retrospective study of Medicare data, Earle and colleagues reported significant increases over time in the proportion of cancer patients with more than one ED visit (7.2 vs. 9.2 %; $P<0.001$), an acute hospitalisation (7.8 vs. 9.1 %; $P=0.008$) or admission to intensive care (7.1 vs. 9.4 %; $P=0.009$) in the last month of life [15]. A number of studies have investigated this trend with several associated factors identifying gender, ethnicity and age as important determinants [20–24]. However, evidence of an association with clinical characteristics and community health care services is limited [25, 26]. The aim of our study was therefore to investigate socio-demographic, clinical and community health care service factors associated with aggressive EOL care for a cohort of 681 cancer decedents.

Methods

Study design and setting

We analysed pooled data from two mortality follow-back studies: the QUALYCARE study [27] and the International Access, Rights and Empowerment (IARE) study [28]. Mortality follow-back studies involve surveying a cohort of decedents' significant others to gain information regarding the EOL [29]. Through their design they address a number of challenges commonly encountered when researching EOL care including the accurate identification of people at the EOL and the often high rates of participant withdrawal (typically due to ill health) that are seen with prospectively designed studies [29, 30]. In both the QUALYCARE and IARE studies, bereaved relatives/significant others were surveyed (via a postal questionnaire) regarding the care received by their family member/friend in the last 3 months of life. Both studies were conducted across London, collectively representing a socially and economically diverse urban population. All participants had access to free health care at the point of delivery through the UK's National Health Service; however, within this broader context, there were important differences between the study samples with regard to the EOL care packages provided; the IARE study sampled patients, all of whom had accessed specialist palliative care services prior to death, whereas the QUALYCARE study included patients who had accessed generalist, specialist or no palliative care services prior to death. Our pooled study sample therefore provided us with information regarding the EOL care experiences of cancer patients across a range of health care packages and levels of palliative care input. Further information regarding each of the original studies is available elsewhere [27, 28].

Study population

Eligibility criteria for each of the original studies are described in Table 3 Appendix. For our analysis, inclusion criteria were as follows: (1) bereaved caregiver aged ≥18 years at time of survey completion, (2) family member/friend died from cancer (ICD-10 codes C00 to C97) and were ≥18 years at time of death, and (3) registration of death occurred 4 to 10 months prior to survey completion.

Bereaved caregivers of patients' whose underlying cause of death was due to non-malignant disease were excluded.

Study questionnaire

The questionnaire was developed using cognitive interviewing for the QUALYCARE study [31] and then adapted for use by the IARE study. Both questionnaire versions include five questions about the deceased's health state 3 months prior to death (using the EuroQol Five-Dimensional Questionnaire (EQ5D-3L) [32]) and several questions regarding the number and type of health care services used during the deceased's last 3 months of life.

Outcome measure and explanatory variables

For our primary outcome, we calculated a composite measure, based on markers of potentially aggressive EOL cancer care developed by Earle and colleagues [5, 33], where we scored each patient one point per occurrence of any of the following three indicators: greater than or equal to two ED visits in the last 3 months of life, ≥30 days in hospital in the last 3 months of life and death in hospital. We then dichotomised the composite score into two groups: those who experienced no indicators of aggressive EOL care (composite score=0) and those who experienced at least one indicator (composite score=1–3).

We examined three groups of variables potentially associated with our primary outcome: socio-demographics, clinical characteristics and community health care service factors.

Socio-demographics included age at death (categorised into five groups; <60 (reference), 60–69, 70–79, 80–89 and 90+ years), gender (reference female), marital status (married or with partner (reference), widowed, divorced/ separated and single) and living circumstances dichotomised as living with others (reference) or living alone. A subjective measure of patients' financial hardship was reported from five possible categories and dichotomised for analysis into those described as living comfortably (reference) compared to all other groups (doing alright, just about getting by, finding it quite difficult and finding it very difficult).

Clinical characteristics included patients' health state 3 months prior to death and underlying cancer diagnosis. Health state was measured using the EQ5D-3L [32] which includes questions on mobility, ability to self-care, activity level, pain/discomfort and anxiety/depression. Underlying type of cancer was categorised into seven groups (lung (reference), breast, prostate, gastrointestinal tract, haematological, unknown primary and other).

Use of community health care services in the last 3 months of life included the number of general practitioner (GP) home visits (categorised as none (reference), one to five and greater than five visits), contact with community palliative care services (yes or no (reference)), and contact with district nursing (yes or no (reference)). Community palliative care services were defined as those that specifically provided palliative and/or EOL care to patients in non-hospital settings and included services such as Hospice at Home and Marie Curie or Macmillan nursing. District nursing was defined as any other nursing care (i.e. not exclusively palliative or EOL care nursing) received by patients in non-hospital settings such as the patients' home.

Statistical analysis

We used summary statistics to report patient demographic data and describe the aggressiveness of EOL care experienced. Differences between patients who did and did not experience aggressive care were tested using a chi-squared test.

The likelihood of patients experiencing aggressive EOL care was investigated using multivariable logistic regression, where we calculated adjusted odds ratios (AORs) and their corresponding 95 % confidence intervals (CIs). Based on findings of a recently published systematic review [24], the logistic model was constructed with the following variables included a priori: age, gender, financial status, marital status, type of cancer and contact with palliative care services. All additional variables were included if found to be significant ($p<0.10$) at univariate analysis. We conducted sensitivity analysis to explore the potential impact to our findings from the two different study samples.

Stata/IC 13 (STATA, College Station, TX, USA) was used for all statistical analysis.

Results

The pooled dataset contains survey responses from 681 bereaved caregivers from across five London health regions (QUALYCARE $n=554$, IARE $n=127$).

Mean age at death was 75 years; 50.1 % were men. Most lived with others prior to death (69.7 %). The two most common diagnoses were gastrointestinal cancer (24.5 %) and lung cancer (21.3 %) (Table 1).

Most patients in our sample (59.3 % (95 % CI 55.6–63.0 %)) experienced at least one indicator of aggressive care during the last 3 months of life: 29.7 % experienced greater than or equal to two ED visits, 17.1 % spent ≥30 days in hospital and 37.9 % died in hospital (Fig. 1). The median composite score of aggressive EOL care was 1 (range 0 to 3).

Relative to those with lung cancer, patients with prostate or haematological cancer were significantly more likely to experience aggressive care during their last 3 months of life (AOR 4.36, 95 % CI 1.39–13.70, and AOR 4.16, 95 % CI 1.38–12.47, respectively). No association was found between aggressive EOL care and cancer patients' health status 3 months prior to death (Table 2).

Patients who had contact with community health care services (GP home visits, district nursing, and community palliative care) were significantly less likely to experience aggressive care during their last 3 months of life (Table 2). For GP home visits, an incremental pattern was found whereby patients with greater than five visits had a greater reduction in odds than those who had one to five visits (AOR 0.37, 95 % CI 0.17–0.82, and AOR 0.59, 95 % CI 0.35–1.00, respectively (reference group no GP home visit)). Compared to patients who had no contact with district nursing, those with contact were less likely to experience aggressive EOL care (AOR 0.48, 95 % CI 0.28–0.83); however, the greatest reduction in odds was found for cancer patients who had contact with community palliative care services (AOR 0.27, 95 % CI 0.15–0.49 (reference group no contact)).

We found no association between aggressive EOL care and cancer patients' age, gender, marital status or financial status (Table 2). No changes to the effect outcomes were found at sensitivity analysis.

Discussion

We used pooled data from two mortality follow-back surveys to examine the aggressiveness of EOL care received by 681

Table 1 Socio-demographics, clinical characteristics and community health care service use of study sample

	Entire cohort		Patients not experiencing any aggressive care		Patients experiencing aggressive care		QUALYCARE cohort		QUALYCARE patients experiencing aggressive care		IARE cohort		IARE patients experiencing aggressive care	
	N	%	*N*	%	*N*	%	*N*	%	*N*	%	*N*	%	*N*	%
	681	100	277	40.7	404	59.3	554	100	299	54.0	127	100	105	82.7
Age in years														
<60	67	9.8	33	11.9	34	8.4	67	12.1	34	11.4	0	0.0	0	0.0
60–69	141	20.7	49	17.7	92	22.8	112	20.2	66	22.1	29	22.8	26	24.8
70–79	191	28.1	69	24.9	122	30.2	140	25.3	82	27.4	51	40.1	40	38.1
80–89	228	33.5	105	37.9	123	30.5	190	34.3	91	30.4	38	29.9	32	30.5
90+	54	7.9	21	7.6	33	8.2	45	8.1	26	8.7	9	7.1	7	6.7
Gender														
Male	341	50.1	127	45.9	214	53.0	282	50.9	166	44.5	59	46.5	48	45.7
Female	340	49.0	150	54.2	190	47.0	272	49.1	133	55.5	68	53.5	57	54.3
Financial status														
Living comfortably	323	48.1	142	51.6	181	45.6	273	49.9	138	46.9	50	40.0	43	41.8
Not living comfortably	349	51.9	133	48.4	216	54.4	274	50.1	156	53.1	75	60.0	60	58.3
Marital status														
Married or with partner	323	50.6	147	54.7	176	47.7	289	53.2	147	50.5	34	35.8	29	37.2
Widowed	191	29.9	77	28.6	114	30.9	154	28.4	84	28.9	37	39.0	30	38.5
Divorced/Separated	59	9.3	20	7.4	39	10.6	47	8.7	29	10.0	12	12.6	10	12.8
Single	65	10.2	25	9.3	40	10.8	53	9.8	31	10.7	12	12.6	9	11.5
Living circumstances														
Living alone	203	30.3	77	28.3	126	31.7	379	69.8	198	67.6	87	69.1	73	70.2
Living with others	466	69.7	195	71.7	271	68.3	164	30.2	95	32.4	39	31.0	31	29.8
Cancer type														
Lung	145	21.3	63	22.7	82	20.3	119	21.5	64	21.4	26	20.5	18	17.1
Breast	52	7.6	28	10.1	24	5.9	47	8.5	20	6.7	5	3.9	4	3.8
Prostate	46	6.8	8	2.9	38	9.4	37	6.7	30	10.0	9	7.1	8	7.6
Gastrointestinal tract	167	24.5	78	28.2	89	22.0	157	28.3	81	27.1	10	7.9	8	7.6
Haematological	54	7.9	9	3.3	45	11.1	34	6.1	28	9.4	20	15.8	17	16.2
Cancer of unknown primary	61	9.0	20	7.2	41	10.2	47	8.5	28	9.4	43	33.9	13	12.4
Other[a]	156	22.9	71	25.6	85	21.0	113	20.4	48	16.1	43	33.9	37	35.2
Mobility at 3 months before death														
No problem	159	24.6	58	21.8	101	26.6	132	25.0	78	27.5	27	23.1	23	24.0
Some problem	423	65.5	176	66.2	247	65.0	350	66.2	184	64.8	73	62.4	63	65.6
Confined to bed	64	9.9	32	12.0	32	8.4	47	8.9	22	7.8	17	14.5	10	10.4
Self-care at 3 months before death														
No problem	262	41.1	93	35.5	169	45.0	212	40.6	128	45.7	50	43.1	41	42.7
Some problem	259	40.6	120	45.8	139	37.0	215	41.2	102	36.4	44	37.9	37	38.5
Unable to self-care	117	18.3	49	18.7	68	18.1	95	18.2	50	17.9	22	19.0	18	18.8
Activity at 3 months before death														
No problem	137	21.3	40	15.2	97	25.6	106	20.2	71	25.2	31	26.5	26	26.8
Some problem	286	44.5	127	48.1	159	42.0	241	45.8	121	42.9	45	38.5	38	39.2
Unable to walk	220	34.2	97	36.7	123	32.5	179	34.0	90	31.9	41	35.0	33	34.0
Pain/Discomfort at 3 months before death														
No pain	113	17.7	46	17.4	67	17.9	97	18.6	54	19.3	16	13.8	13	13.7
Some pain	392	61.4	158	59.9	234	62.4	322	61.6	179	63.9	70	60.3	55	57.9
Extreme pain	134	21.0	60	22.7	74	19.7	104	19.9	47	16.8	30	25.9	27	28.4

Table 1 (continued)

	Entire cohort		Patients not experiencing any aggressive care		Patients experiencing aggressive care		QUALYCARE cohort		QUALYCARE patients experiencing aggressive care		IARE cohort		IARE patients experiencing aggressive care	
	N	%	*N*	%	*N*	%	*N*	%	*N*	%	*N*	%	*N*	%
	681	100	277	40.7	404	59.3	554	100	299	54.0	127	100	105	82.7
Anxiety/Depression at 3 months before death														
No anxiety/depression	223	35.5	91	35.1	132	35.8	176	34.1	97	35.0	47	42.0	35	38.0
Some anxiety/depression	316	50.3	128	49.4	188	51.0	267	51.7	146	52.7	49	43.8	42	45.7
Extreme anxiety/depression	89	14.2	40	15.4	49	13.3	73	14.2	34	12.3	16	14.3	15	16.3
Number of GP home visits during the last 3 months of life														
None	181	31.4	46	19.1	135	40.3	138	29.2	96	37.9	43	41.8	39	47.6
1–5	338	58.7	159	66.0	179	53.4	287	60.7	141	55.7	51	49.5	38	46.3
>5	57	9.9	36	14.9	21	6.3	48	10.2	16	6.3	9	8.7	5	6.1
Community palliative care														
No	205	31.2	36	13.2	169	43.9	156	29.0	121	42.2	49	40.8	48	49.0
Yes	453	68.8	237	86.8	216	56.1	382	71.0	166	57.8	71	59.2	50	51.0
District nurse														
No	227	34.7	56	20.8	171	44.4	172	32.2	121	42.2	55	45.8	50	51.0
Yes	427	65.3	213	79.2	214	55.6	362	67.8	166	57.8	65	54.2	48	49.0

[a] Other cancers included those of the urinary tract (5.0 %), gynaecological (3.8 %), central nervous system (3.8 %) and skin (1.8 %) with percentage figures referring to entire cohort data

deceased cancer patients. We found statistically and clinically significant variations based on patients' underlying cancer type and their contact with community health care services.

Supporting previously published studies, we found that patients with haematological cancers were more likely to experience aggressive EOL care compared to those with lung cancer [16, 34]. Features related to both the disease process and the discipline of haemato-oncology are likely to contribute to this effect, for example, chemotherapy remains the main and often only form of therapy available, clinical trial involvement is particularly high and haemato-oncology clinical services have historically remained distinct from those of solid tumours with less collaboration between disciplines, including with palliative care [35]. Our finding that patients with prostate cancer also have an increased risk of experiencing aggressive EOL care is interesting, and additional research exploring patterns of acute care towards the EOL by cancer sub-groups is warranted. In our sample, although the proportion of prostate cancer patients who spent ≥30 days in hospital during the last 3 months of life was similar to patients with other cancer types, we found that prostate cancer patients were more likely to have greater than or equal to two ED visits in the last 3 months of life and/or die in hospital (Table 4 Appendix). Metastatic bone disease is commonly seen in patients with advanced prostate cancer, and complications from this pattern of disease spread, in particular pathological fractures, typically result in ED visits. This may explain some of the higher rates of ED use that we found in our sub-group of prostate cancer patients; however, further research exploring this finding is required. Our finding of lower odds of aggressive EOL care associated with GP home visits supports Almaawiy and colleagues [25]. In their study of 9467 cancer decedents in Canada, increased family physician visits were associated with reduced odds for both hospital death and an ED visit in the last 2 weeks of life [25]. However, Almaawiy et al. found that patients with greater than four visits per week had increased odds of hospitalisations and hospital death, the opposite of our study which found that care was less aggressive for patients who had greater than five GP home visits than for those who had one to five or no GP visits.

Our data support growing observational and experimental evidence that community palliative care is associated with lower odds of aggressive EOL care [9, 24, 36, 37]. Expansion of palliative care services may therefore be one approach towards helping address the current capacity crises faced by many acute health care systems. Of note, the effect size found in our study (AOR 0.27, 95 % CI 0.15–0.49) was greater than those previously reported which may be related to our study time period (the last 3 months of life) as this is longer than those reported by several similar studies [20, 37]. This is particularly relevant given the small but emerging body of evidence indicating a greater reduction in risk of patients

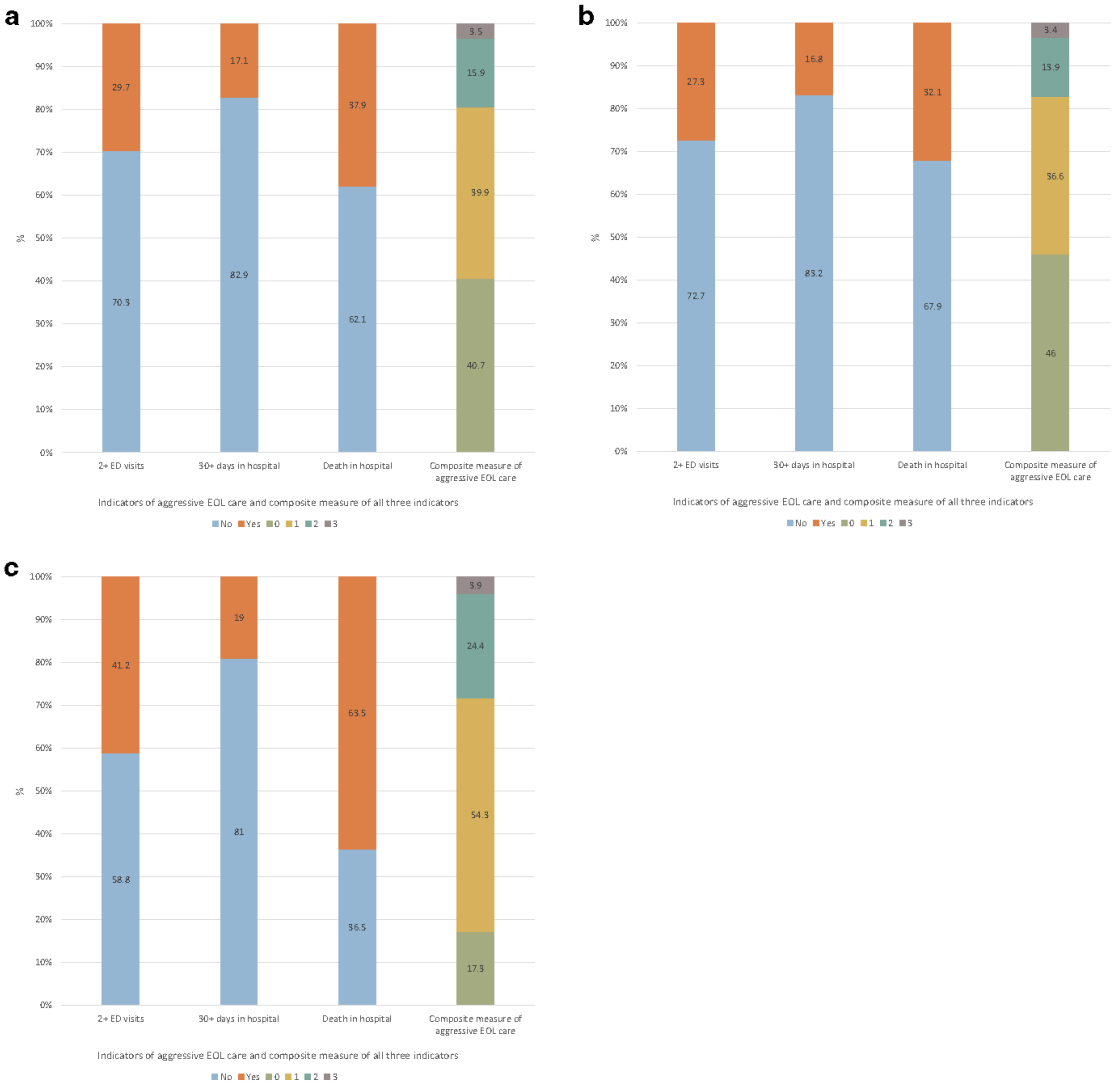

Fig. 1 **a** Graph showing number of patients experiencing greater than or equal to two emergency department (ED) visits in the last 3 months of life, ≥30 days spent in hospital in the last 3 months of life and death in hospital, and composite measure of aggressive end of life (EOL) care calculated from these indicators for entire study cohort. **b** Graph showing number of patients experiencing greater than or equal to two ED visits in the last 3 months of life, ≥30 days spent in hospital in the last 3 months of life and death in hospital, and composite measure of aggressive EOL care calculated from these indicators for the QUALYCARE cohort of sample. **c** Graph showing number of patients experiencing greater than or equal to two ED visits in the last 3 months of life, ≥30 days spent in hospital in the last 3 months of life and death in hospital, and composite measure of aggressive EOL care calculated from these indicators for the IARE cohort of sample

receiving aggressive EOL care with earlier palliative care involvement [9, 37, 38]. Further investigation of the effect according to timing of palliative care interventions is necessary.

Several previously published studies have reported that men and patients of lower financial status have an increased risk of experiencing aggressive EOL care [15, 16, 20–22, 25, 26, 34]. In our study, although we found a similar pattern, our results for these factors did not reach statistical significance. This may be related to our study sample size which when compared to similar studies reporting significant findings is much smaller, with the later mostly analysing population-based routinely collected data. We also used a subjective measure of financial hardship which in health research in less common than objective socio-economic status measures

Table 2 Findings from multivariable analysis for factors associated with cancer patients experiencing aggressive care during the last 3 months of life

Variable	OR	95 % CI	AOR	95 % CI
Age in years				
<60	1.00	–	–	–
60–69	1.82	1.00–3.32	1.82	0.82–4.03
70–79	1.72	0.97–3.03	1.70	0.78–3.71
80–89	1.14	0.66–1.96	0.98	0.45–2.13
>90	1.53	0.73–3.18	1.44	0.49–4.26
Gender				
Female	1.00	–	–	–
Male	1.33	0.98–1.81	1.35	0.84–2.18
Financial status				
Living comfortably	1.00	–	–	–
Not living comfortably	1.27	0.94–1.74	1.34	0.88–2.05
Marital status				
Married or with partner	1.00	–	–	–
Widowed	1.24	0.86–1.78	1.50	0.85–2.65
Divorced/Separated	1.63	0.91–2.92	1.04	0.48–2.24
Single	1.34	0.77–2.31	1.65	0.70–3.88
Cancer type				
Lung	1.00	–	–	–
Breast	0.66	0.35–1.25	0.98	0.38–2.52
Prostate	3.65	1.55–8.58	**4.36**	**1.39–13.70**
Gastrointestinal tract	0.88	0.56–1.37	1.35	0.74–2.44
Haematological	3.84	1.70–8.68	**4.16**	**1.38–12.47**
Cancer of unknown primary	1.58	0.84–2.96	1.34	0.62–2.92
Other	0.92	0.58–1.45	0.91	0.48–1.74
Self-care at 3 months before death				
No problem	1.00	–	–	–
Some problem	0.64	0.45–0.91	0.93	0.53–1.62
Unable to self-care	0.76	0.49–1.19	1.43	0.63–3.22
Activity at 3 months before death				
No problem	1.00	–	–	–
Some problem	0.52	0.33–0.80	0.74	0.40–1.39
Unable to walk	0.52	0.33–0.83	0.69	0.31–1.49
Number of GP home visits during the last 3 months of life				
None	1.00	–	–	–
1–5	0.38	0.26–0.58	**0.59**	**0.35–1.00**
>5	0.20	0.10–0.39	**0.37**	**0.17–0.82**
Community palliative care				
No	1.00	–	–	–
Yes	0.19	0.13–0.30	**0.27**	**0.15–0.49**
District nurse				
No	1.00	–	–	–
Yes	0.33	0.23–0.48	**0.48**	**0.28–0.83**

Numbers in bold represent statistically significant findings, $p<0.05$

OR odds ratio, *95 % CI* 95 % confidence interval, *AOR* adjusted odds ratio

[39]. Subjective assessments of financial status are valid alternatives to objective measures and are particularly valuable when objective measures, which require responses to multiple questions and are prone to having high levels of missing data,

are felt to be inappropriate [40, 41]. The lack of association found between patient age and aggressive EOL care is inconsistent with the wider scientific literature where a decrease in aggressiveness with increasing patient age has generally been reported [15, 17, 20, 42, 43]. This requires further investigation but may reflect a specific change in UK policy towards cancer treatment for older people, with equality legislation in 2012 [44].

We also found no association between aggressive EOL care and cancer patients' health status (mobility, ability to self-care, activity level, pain/discomfort and anxiety/depression) 3 months prior to death, suggesting that socio-demographic and/or environmental factors may be of greater importance when determining the type of care that patients are likely to receive towards the EOL. In a systematic review of place of death by Gomes and Higginson in 2006, environmental factors were also found to be more influential than factors relating to the underlying illness [45]. These findings have important policy implications when considering how future acute health care services are delivered, especially given the ageing population and anticipated rise in cancer cases [46].

Limitations

Mortality follow-back surveys have recognised limitations primarily relating to the validity of bereaved caregivers' responses as proxies for the decedents. For objective measures, caregiver responses have been shown to have moderate to good agreement with patients'; however, for subjective experiences, such as pain or anxiety, less overall agreement has been reported and it is therefore possible that the responses received in our study may not be truly representative of the patients' experiences at that time [47, 48].

As is the case with all secondary analysis, our choice of variables was limited by the data collected for the purposes of the primary studies. For our dependent variable, this meant that two of the three EOL care indicators that we used to calculate our composite outcome measure have not themselves been validated (greater than or equal to two ED visits in the last 3 months of life and ≥30 days in hospital in the last 3 months). However, both indicators were considered to be clinically relevant and were based on well-established validated markers [5, 33]. The third indicator, death in hospital, is commonly used as a marker of potentially aggressive EOL care arising from consistent evidence that the majority of cancer patients would prefer to die at home [49]. With regard to the independent variables investigated, we explored socio-demographic factors, clinical characteristics and patient receipt of GP home visits, district nursing and community palliative care. Further information regarding the local availability of health and social care services was not available. As our study included patients from across London, it is therefore possible that regional variations in care provision, for example, bed availability and/or community hospice services, may have influenced the parameters that we used to define our primary outcome of aggressive EOL care. Finally, because of the different sampling approaches used by each of the primary studies, the prevalence of aggressive EOL care in our pooled sample may not be representative of, and therefore generalisable to, the wider cancer population. However, these different sampling approaches were not expected to impact the factors associated with aggressive EOL care which was the primary focus of our study, and benefits to pooling the datasets included being able to explore the EOL care experiences of patients receiving a range of different health care packages including various levels of palliative care input. Furthermore, the QUALYCARE study sampled participants according to place of death, with deaths in hospital undersampled. It is therefore likely that our estimation of aggressive EOL care, which included death in hospital as one of its indicators, is actually lower than that of the true population.

Conclusions

Our results reveal an association between aggressive care in the last 3 months of life and a diagnosis of prostate or haematological cancer. We also found that community health care services, in particular contact with community palliative care, are associated with a significant reduction in the odds of cancer patients receiving aggressive care towards the EOL. Expansion of such services may help address the current capacity crises faced by many acute health care systems. Contrary to earlier studies, we found that older age did not appear to influence the risk of cancer patients receiving aggressive EOL care.

Acknowledgments This study was conducted as part of the project BuildCARE; supported by Cicely Saunders International and The Atlantic Philanthropies, led by King's College London, Cicely Saunders Institute, Department of Palliative Care, Policy and Rehabilitation, UK. CI: Higginson. Grant leads: Higginson, McCrone, Normand, Lawlor, Meier and Morrison. Project Co-ordinator/principal investigator (PI): Daveson. Study arm PIs: Pantilat, Selman, Normand, Ryan, McQuillan, Morrison and Daveson. We thank all collaborators and advisors including service users. BuildCARE members: Emma Bennett, Francesca Cooper, Barbara A Daveson, Susanne de Wolf-Linder, Mendwas Dzingina, Clare Ellis-Smith, Catherine J Evans, Taja Ferguson, Lesley A Henson, Irene J Higginson, Bridget Johnston, Paramjote Kaler, Pauline Kane, Peter Lawlor, Paul McCrone, Regina McQuillan, Diane Meier, Sean Morrison, Fliss E Murtagh, Charles Normand, Caty Pannell, Steve Pantilat, Ana Reison, Karen Ryan, Lucy Selman, Melinda Smith, Katy Tobin, Rowena Vohora and Gao Wei.

This study involved data from two studies: the QUALYCARE study and the IARE study. We thank all participants, the researchers (Natalia Calanzani, Paul McCrone, Sue Hall, Caty Pannell, Melinda Smith and Susanne de Wolf-Linder) and the funders of these original studies (Cicely Saunders International and The Atlantic Philanthropies).

Conflict of interest The authors indicate no potential conflicts of interest.

Funding This study was supported by Cicely Saunders International, The Atlantic Philanthropies, Marie Curie Cancer Care and the Collaboration for Leadership in Applied Health Research and Care (CLAHRC) South London, National Institute for Health Research (NIHR). The CLAHRC is a partnership between King's Health Partners, St George's, University of London, and St George's Healthcare NHS Trust.

Author contributions Conception and design: Lesley A Henson, Wei Gao and Irene J Higginson.

Collection and assembly of data: all authors.

Data analysis: Lesley A Henson, supported by Wei Gao, Barbara Gomes and Irene J Higginson.

Data interpretation: all authors.

Manuscript writing: Lesley A Henson and Wei Gao supported by Irene J Higginson, with critical revisions by all other authors.

Final approval of manuscript: all authors.

Appendix

Table 3 Eligibility criteria for each of the primary studies included in secondary analysis

	Eligibility criteria	Additional comments
QUALYCARE [27] Study participants: Bereaved relatives of people aged ≥18 years who died from cancer over a 1-year period and who lived in one of four London Primary Care Trusts: Bromley, Islington, Sutton and Merton or Westminster	Inclusion criteria 1.Deceased last resident in one of the four following Primary Care Trusts as recorded in the death registration: Bromley, Islington, Sutton and Merton or Westminster. 2.Date of death registration within 4 to 10 months before sampling. 3.Deceased aged ≥18 at time of death. 4.Cancer (ICD10 codes C00–D48) recorded as 'underlying cause of death' or in the lowest completed cause of death line in death certificate. Exclusion criteria 1.Place of death other than an NHS acute hospital, the deceased's own home, hospice or nursing home. 2.Place of death unknown. 3.Deaths registered by a coroner.	The four Primary Care Trusts were specifically chosen as they provided contrasting cancer home death rates and contrasting deprivation levels within London. The study sample was then stratified by Primary Care Trust and place of death so that in each area the sample included all deaths that occurred at home, all hospice deaths, all nursing home deaths, and a random sample of NHS acute hospital deaths.
IARE [28] Study participants: Bereaved carers of older patients who had accessed specialist palliative care prior to death.	Inclusion criteria 1.Deceased aged ≥65 years at time of death and had accessed specialist palliative care prior to death. 2.Main informal carer aged ≥18 years and known to the palliative care team as the primary informal carer that was most involved in providing information and unpaid care for the patient. 3.Date of death registration within 4 to 10 months before sampling. Exclusion criteria 1.Adults who did not provide informal (unpaid) care of an eligible patient. 2.Carers aged <18 years.	

Table 4 Number of patients experiencing greater than or equal to two emergency department (ED) visits in the last 3 months of life, ≥30 days spent in hospital in the last 3 months of life and death in hospital for each cancer type

	Entire cohort	Patients with greater than or equal to two ED visits in the last 3 months of life		Patients who spent ≥30 days in hospital in the last 3 months of life		Patients who died in hospital	
	N	*N*	%	*N*	%	*N*	%
	681	194	29.8	108	15.9	258	38.0
Cancer type							
Lung	145	37	26.6	15	10.3	53	36.6
Breast	52	10	20.0	4	7.7	13	25.0
Prostate	46	22	52.4	11	23.9	27	58.7
Gastrointestinal tract	167	42	25.3	27	16.2	52	31.1
Haematological	54	18	38.3	16	29.6	32	59.3
Cancer of unknown primary	61	24	39.3	11	18.0	26	42.6
Other[a]	156	41	27.9	24	15.4	55	35.5

[a] Other cancers included those of the urinary tract (5.0 %), gynaecological (3.8 %), central nervous system (3.8 %) and skin (1.8 %) with percentage figures referring to entire cohort data

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Chapter 5 - What Factors Influence Emergency Department Visits by Patients with Cancer at the End of Life? Analysis of a 124,030 Patient Cohort [PUBLICATION 3]

Original Article

PALLIATIVE MEDICINE

Palliative Medicine
1–13

DOI: 10.1177/0269216317713428
journals.sagepub.com/home/pmj
SAGE

What factors influence emergency department visits by patients with cancer at the end of life? Analysis of a 124,030 patient cohort

Lesley A Henson, Irene J Higginson and Wei Gao; on behalf of BuildCARE

Abstract

Background: Emergency department visits towards the end of life by patients with cancer are increasing over time. This is despite evidence of an association with poor patient and caregiver outcomes and most patients preferring home-based care.

Aim: To identify socio-demographic and clinical factors associated with end-of-life emergency department visits and determine the relationship between patients' prior emergency department use and risk of multiple ($\geq$2) visits in the last month of life.

Design: Population-based cohort study.

Setting/participants: All adults who died from cancer, in England, between 1 April 2011 and 31 March 2012. Our primary outcome was the adjusted odds ratio for multiple emergency department visits in the last month of life, derived using multivariable logistic regression.

Results: Among 124,030 cancer decedents (52.9% men; mean age: 74.1 years), 30.7% visited the emergency department once in their last month of life and 5.1% visited multiple times. Patients were more likely to visit multiple times if they were men, younger, Asian or Black, of lower socio-economic status, had greater comorbidity, and lung or head and neck cancer. Patients with $\geq$4 emergency department visits in the 11 months prior to their last month of life were also more likely to make multiple visits during their last 30 days; this followed a dose–response pattern (p for trend $<$0.001).

Conclusion: Patients with greater comorbidity, lung or head and neck cancer and a higher number of previous emergency department visits are more likely to visit the emergency department multiple times in the last month of life. Previously reported socio-demographic factors (men, younger age, Black, low socio-economic status) are also confirmed for the first time in a UK population.

Keywords

Cancer, end-of-life care, emergency department, Accident & Emergency, palliative care, health behaviour

What is already known about the topic?

- Emergency department (ED) visits towards the end of life by patients with cancer are increasing over time. This is despite:
  - An association with poor patient and caregiver outcomes;
  - The majority of patients preferring home-based care;
  - Most EDs facing significant financial and capacity constraints.

What this paper adds?

- This study identifies socio-demographic (male sex, younger age, Asian or Black ethnicity, lower socio-economic status) and clinical factors (greater comorbidity, and diagnosis of lung or head and neck cancer) associated with an increased odds of multiple ($\geq$2) ED visits by patients with cancer in the last month of life.

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- Patients with a higher number of previous ED visits were also found to have a greater odds of multiple ED visits in the last month of life (adjusted odds ratio for ⩾7 previous visits 1.81, 95% confidence interval 1.58–2.07, reference no visits); this followed a dose–response pattern (p for trend <0.001).

Implications for practice, theory or policy

- These findings can help healthcare professionals, managers and policy-makers to identify patients at increased risk of multiple ED visits towards the end of life, therefore allowing additional support services and/or alternative care pathways to be provided.
- Further research exploring the mechanism of action for the risk factors identified is required.

Introduction

In 2012, an estimated 8.2 million people died from cancer worldwide.[1] Population growth and ageing mean that global cancer mortality is expected to rise further, increasing to an anticipated 14.6 million deaths by 2035.[1] Issues pertaining to end-of-life care are consequently affecting a greater number of cancer patients each year, and the importance of providing high-quality care, in accordance with patients' needs and preferences, is increasingly recognised.[2]

Towards the end of life, people with cancer wish to be comfortable, spend time with their loved ones and have access to emotional and spiritual support as required.[3–5] Most (64%–84%) prefer to be cared for and die at home,[6–9] and to avoid overly 'aggressive' care, which can be defined as care that focuses mostly or exclusively on disease-modifying treatments at the expense of good symptom management and/or advance care planning.[4,10,11] In addition to patients' preferences, studies have found overly aggressive end-of-life cancer care to be associated with poor patient and caregiver outcomes, including prolonged pain, overall dissatisfaction with care and more than three times the odds of psychiatric illness in bereaved relatives.[12–14]

Less is known about the factors that may influence aggressive end-of-life cancer care. Quantifying the aggressiveness of end-of-life cancer care is in itself challenging. Disease-related complications, adverse effects of treatment and/or unrelated health conditions are all commonly experienced by patients with advanced cancer. To be optimally managed, many of these situations require hospital-based care. Deciding which hospital visits represent high-quality care versus those that signify overly aggressive care is complicated: good quality care for one patient may be considered overly aggressive by the next. To address this issue, Earle et al.[11,15] developed a set of quality indicators which, at a population-level, could be used to identify healthcare systems delivering overly aggressive end-of-life cancer care. In 2012, five of these performance measures were endorsed by the National Quality Forum in the United States.[16] To date, these measures have not been used to examine the aggressiveness of end-of-life cancer care within the National Health Service (NHS); a unique healthcare system that provides healthcare free for all at the point of delivery.

This study seeks to understand and improve the quality of end-of-life cancer care by focusing on one of these validated performance measures – the proportion of cancer patients with multiple (⩾2) emergency department (ED) visits in the last month of life. This measure was chosen because ED visits often represent patients' first contact with a healthcare professional when experiencing an acute or urgent symptom. This time is therefore critical when deciding factors such as place of care and intensity of treatment.[17] Furthermore, ED visits in general and advanced cancer populations are rising,[18–21] despite concerns of ED overcrowding and capacity constraints.

In order to develop future services that can effectively reduce avoidable ED visits (while also supporting appropriate attendance for those in need), a comprehensive understanding of the factors influencing cancer patients' ED visits is required. Knowledge of such factors could help healthcare professionals identify individuals at increased risk of multiple end-of-life ED visits, therefore allowing additional support services to be provided. In an earlier systematic review, we identified 21 factors associated with ED visits by cancer patients in the last month of life.[22] Our findings were, however, limited by the high proportion of studies conducted in the United States and Canada, and conflicting results relating to patients' comorbidity, cancer diagnosis and rurality of usual place of residence. In order to address these gaps and allow development of more targeted approaches towards reducing end-of-life ED visits, we conducted a retrospective cohort study of 124,030 cancer decedents in England, UK. The aim of our study was to determine socio-demographic factors and clinical characteristics associated with end-of-life ED visits and explore the relationship between patients' prior ED use and the risk of multiple ED visits in the last month of life.

Methods

Our paper is reported following the RECORD statement – a checklist extended from STROBE and specific to reporting of observational studies using routinely collected health data.[23,24]

Approval for the study was received from NHS Digital (reference no. NIC-223311-Z0B8Q). As all data were pseudonymised, and therefore non-identifiable, no further approvals were required to complete the analysis.

Design

This is a population-based retrospective cohort study.

Data sources

We used linked patient-level data from two routinely collected databases: the Office for National Statistics (ONS) Mortality Database and Hospital Episode Statistics (HES) Accident & Emergency Database.[25,26] The ONS Mortality Database holds information on all UK deaths based on the information collected when a death is registered. It includes the 'original underlying cause of death' – that is the medical condition judged as the disease/injury leading directly to death or circumstances of an accident or violence that resulted in fatal injury.[25] HES Accident & Emergency Database contains detailed patient-level data for all visits to NHS EDs in England, UK. It includes both clinical data and information regarding the circumstances of a visit, for example, date and time.[27] Linking ONS and HES data allows for analysis of patients' hospital activity prior to death and is possible through matching person identifiable data in ONS with patient identifiers in HES. During the linkage process, each record is assigned a match rank between one (best match) and eight (worse match), providing an indication of the level of confidence that the records have been matched correctly. Over 90% of linked ONS-HES records receive a match rank of one (requiring an exact match of date of birth, sex, NHS number and postcode) or two (requiring an exact match of date of birth, sex and NHS number).[28]

Study cohort

Our cohort, supplied by ONS, included all adults (≥18 years) who died from cancer (International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10), codes for underlying cause of death C00 to C97)[29] in England, during a 1-year period (1 April 2011–31 March 2012) and had a valid record in HES. This cohort was linked to HES Accident & Emergency data for the same year and the preceding year, that is, 1 April 2010–31 March 2012. This allowed us to quantify the number of ED visits each cancer decedent made in their last year of life.

We excluded persons whose usual place of residence was outside England. We also excluded potentially inaccurate cases, including those with a data linkage match rank of three to eight, cases where patient activity was listed in the HES Accident & Emergency Database after the ONS recorded date of death, and cases where the date of death registration was more than 1 year after the documented date of death.

Variables

Outcome variable. Our primary outcome was the number of unplanned ED visits made by patients with cancer during their last month of life, dichotomised for analysis into those with none or one visit versus those with multiple (≥2) visits.[15] Planned ED visits – defined by HES as 'subsequent organised visits to the same department and for the same incident as the first visit' – were excluded.[27]

Explanatory variables. Models of health seeking behaviour, including those specific to the ED, guided our selection of independent variables.[30,31] We considered three groups of variables: socio-demographic factors, clinical characteristics, and patients' prior ED visits.

Socio-demographic factors included sex (female reference), age at death (<65 (reference), 65–74, 75–84 and 85+ years), ethnicity (White (reference), Asian, Black and other), region of England (North East, North West, Yorkshire and Humberside, East Midlands, West Midlands, East of England, London (reference), South East and South West), rurality of patients' usual place of residence (urban – settlements with populations ≥10,000; rural – settlements with populations <10,000 (reference)) and socio-economic status which we derived from Index of Multiple Deprivation (IMD) quintiles (1 – most deprived; 5 – least deprived (reference)).[32] The IMD is an area-based measure of deprivation that uses Lower Super Output Area (LSOA) geography to compare deprivation between neighbourhoods in England.[33]

Clinical characteristics included cancer diagnosis, level of comorbidity and reason for ED visit, that is, patients presenting symptom or medical condition. Cancer diagnosis was provided by ONS as an ICD-10 code representing the patients' underlying cause of death and was categorised into 12 groups: lung, breast, colorectal (reference), head and neck, haematological, upper gastrointestinal (including oesophagus and stomach), gynaecological, prostate, urinary tract (including kidney), hepatobiliary, pancreas and other. Similar to previous studies using HES data,[34,35] we calculated patients' level of comorbidity using the Deyo modification of the Charlson comorbidity score with the points for malignant disease deducted.[36,37] The score was calculated from data supplied by HES and encompassed a time period of up to 2 years prior to death. Patients were categorised into three groups: those with a

comorbidity score of zero (reference), one or two plus. The reason for ED visit was provided by HES as either an ICD-10 code or a HES generated six-character code that comprised information about the clinical condition (from 58 possible options), anatomical area and side of body. These were grouped into 14 categories: respiratory; cardiovascular; diabetes and endocrinology; gastroenterology and hepatobiliary; genitourinary; haematology; ear nose and throat, facio-maxillary, ophthalmology and/or dermatology; neurology; musculoskeletal disorders and/or injuries; psychiatry and/or social problems; infection; pain; cancer/tumour; and other.

Patients' prior ED use was assessed as a single variable – the total number of ED visits made during the patient's last year of life, excluding those in the last 30 days (reference group zero visits).

Theoretical framework. This study was guided by Andersen and Newman's 'Behavioural Model of Health Services Use'.[38] In this model, healthcare use is presented as a function of need, enabling resources and predisposing characteristics. As such, we hypothesised that cancer patients' end-of-life ED attendance would be influenced by their clinical characteristics, environmental factors and demographics.

Statistical analysis

Counts and percentages were used to describe cancer patients with none, one or multiple ED visits in the last month of life. The differences between patients with multiple ED visits and without (none or one ED visit combined) were explored using chi-square test. Factors associated with multiple ED visits were investigated using multivariable logistic regression, where we calculated adjusted odds ratios (AORs) and their corresponding 95% confidence intervals (CIs). Based on the findings of our recently published systematic review,[22] the multivariable logistic model included the following variables a-priori: age, gender, ethnicity, socio-economic status, type of cancer and level of comorbidity. Additional variables were added if significant ($p < 0.05$) at bivariate analysis.

We calculated variance inflation factors (VIFs) to estimate how much of the variance of the regression coefficient was inflated due to correlation between explanatory variables in the model. We considered VIFs >2.5 to be indicative of multicollinearity.[39] The model's goodness-of-fit was assessed using the Hosmer–Lemeshow test.[39] Discrimination performance was calculated as area under the receiver operating characteristic (ROC) curve. In this technique, the discrimination of the model is assessed by plotting the sensitivity of the test against 1 minus the specificity. The greater the area under the ROC curve (on a scale of 0.5–1), the better the model's discrimination. Levels of missing data were examined and as ≤4% complete-case analysis performed. Stata/IC 13 (STATA, College Station, TX) was used for all statistical analysis.

Results

Between 1 April 2011 and 31 March 2012, there were 135,094 deaths from cancer in England of which 129,042 (95.5%) had a valid record in HES. Patients with no record in any HES database were considered potentially inaccurate and therefore excluded.[40] A further 5012 cases were excluded for other reasons (as described in Figure 1), leaving 124,030 cases suitable for analysis (Figure 1).

Among our cohort, mean age at death was 74.1 years (standard deviation: 12.6); 52.9% were men. Almost all were White (96.1%) and the majority lived in an urban setting (78.2%). The most common cause of death was from lung cancer (21.5%) (Table 1).

In the last month of life, 30.7% ($n = 38{,}049$) of patients visited the ED once, 4.5% ($n = 5561$) made two visits, 0.5% ($n = 654$) made three and 0.1% ($n = 110$) made four or more. The number of visits ranged from 0 to 8 (median: 0).

Multivariable analysis found an association between multiple ED visits in the last month of life and the following socio-demographic factors: younger age, male sex (AOR: 1.26, 95% CI: 1.19–1.34), Asian (AOR: 1.49, 95% CI: 1.27–1.74) or Black ethnicity (AOR: 1.21, 95% CI: 1.01–1.46), lower socio-economic status and living in an urban setting (AOR: 1.18, 95% CI: 1.10–1.28) (Table 2). Patients living in London were significantly more likely to visit the ED multiple times during their last month of life compared to those living in all other regions of England (Table 2).

Clinical characteristics associated with multiple ED visits were a greater level of comorbidity and a diagnosis of lung (AOR: 1.74, 95% CI: 1.56–1.95) or head and neck cancer (AOR: 1.67, 95% CI: 1.40–2.00) (Table 2). For the variable 'reason for ED visit', 1271 patients left of were transferred from the ED before being seen and 1909 patients either died in the ED or were dead on arrival. After excluding these patients, we found that respiratory conditions (19.6%), gastrointestinal and hepatobiliary conditions (13.3%), and musculoskeletal disorders/injuries (including fractures) (11.8%) were most commonly reported. However, this information was not included in our multivariable model due to there also being high levels of missing and/or invalid data.

A dose–response pattern was found for the association between patients' prior ED visits and their attendance in the last month of life. Compared to patients with no ED visits in the 11 months prior to the last month of life, the odds of multiple ED visits during their last 30 days increased with each additional visit, p for trend <0.001 (Figure 2).

Our multivariable model had a good overall fit (Hosmer–Lemeshow test, $\chi^2 = 8.78$, $p = 0.36$). Discrimination

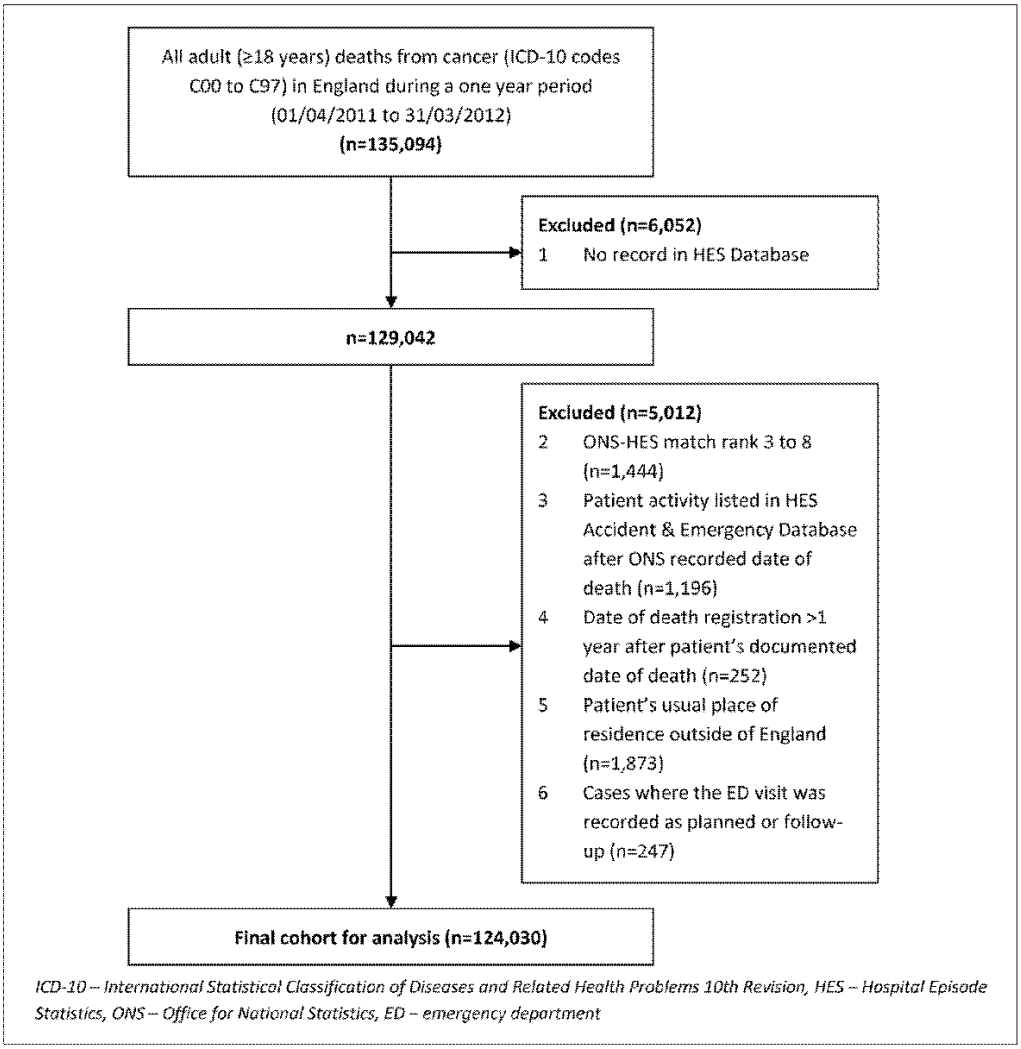

Figure 1. Flow diagram.

performance, calculated as area under the ROC curve, was 0.64. All VIFs were ≤2.5 (mean 1.6).

Discussion

In this population-based cohort study, we investigated socio-demographic factors and clinical characteristics associated with end-of-life ED visits and explored the relationship between patients' prior ED use and the risk of multiple ED visits in the last month of life. We found a dose–response relationship between patients' prior ED use and their end-of-life ED visits, as well as an increased risk of multiple ED visits during the last month of life for patients with greater comorbidity and a diagnosis of lung or head and neck cancer. Previously reported socio-demographic factors (men, younger age, Black ethnicity, low socio-economic status) were also confirmed for the first time in a UK population. Consistent with our study's theoretical framework, we found cancer patients' end-of-life ED visits were influenced by clinical, environmental

Table 1. Socio-demographic factors and clinical characteristics of study cohort ($N = 124,030$).

	Total sample	Emergency department visits in last 30 days					
		None		1 visit		⩾2 visits	
	N	*N*	(%)	*N*	(%)	*N*	(%)
	124,030	79,656	64.2	38,049	30.7	6325	5.1
Age in years, mean (SD)	74.1 (12.6)	74.2 (12.6)		74.4 (12.3)		72.0 (13.1)	
Age in years							
<65	27,528	17,592	63.9	8189	29.8	1747	6.4
65–74	31,499	20,059	63.7	9710	30.8	1730	5.5
75–84	39,764	25,703	64.6	12,233	30.8	1828	4.6
85+	25,239	16,302	64.6	7917	31.4	1020	4.0
Gender							
Male	65,649	40,990	62.4	20,928	31.9	3731	5.7
Female	58,381	38,666	66.2	17,121	29.3	2594	4.4
Ethnicity							
White	114,691	73,865	64.4	35,058	30.6	5768	5.0
Asian	1793	916	51.1	686	38.3	191	10.7
Black	1486	753	50.7	591	39.8	142	9.6
Other	1383	782	56.5	500	36.2	101	7.3
Cancer type							
Lung	26,643	15,525	58.3	9347	35.1	1771	6.7
Breast	8852	5909	66.8	2528	28.6	415	4.7
Colorectal	12,135	8469	69.8	3234	26.7	432	3.6
Head and neck	2789	1782	63.9	814	29.2	193	6.9
Haematology	10,074	6186	61.4	3379	33.5	509	5.1
Upper GI (inc oesophagus and stomach)	12,101	7959	65.8	3526	29.1	616	5.1
Gynaecological	5939	4183	70.4	1525	25.7	231	3.9
Prostate	8596	5678	66.1	2517	29.3	401	4.7
Urinary tract (inc kidney)	7384	4825	65.3	2247	30.4	312	4.2
Hepatobiliary	3835	2462	64.2	1178	30.7	195	5.1
Pancreas	6729	4424	65.8	1977	29.4	328	4.9
Other	18,953	12,254	64.7	5777	30.5	922	4.9
Comorbidity score[a]							
0	52,616	36,154	68.7	14,322	27.2	2140	4.1
1	37,973	23,675	62.4	12,200	32.1	2098	5.5
2+	32,053	18,879	58.9	11,107	34.7	2067	6.5
Number of previous ED visits[b]							
0	44,329	27,333	61.7	15,002	33.8	1994	4.5
1	35,877	24,300	67.7	9928	27.7	1649	4.6
2	20,333	13,371	65.8	5924	29.1	1038	5.1
3	10,692	6914	64.7	3148	29.4	630	5.9
4	5667	3550	62.6	1753	30.9	364	6.4
5	2984	1811	60.7	951	31.9	222	7.4
6	1628	968	59.5	517	31.8	143	8.8
7+	2520	1409	55.9	826	32.8	285	11.3
Socio-economic status (IMD quintile)							
1 – most deprived	23,994	14,246	59.4	8205	34.2	1543	6.4
2	24,534	15,178	61.9	7952	32.4	1404	5.7
3	26,075	17,127	65.7	7732	29.7	1216	4.7
4	25,731	17,130	66.6	7450	29.0	1151	4.5
5 – least deprived	23,612	15,914	67.4	6688	28.3	1010	4.3
Region							
North East	7410	4741	64.0	2253	30.4	416	5.6
North West	18,003	11,014	61.2	5951	33.1	1038	5.8
Yorkshire and Humberside	13,347	9267	69.4	3554	26.6	526	3.9

Table 1. (Continued)

	Total sample	Emergency department visits in last 30 days					
		None		1 visit		⩾2 visits	
	N	*N*	(%)	*N*	(%)	*N*	(%)
	124,030	79,656	64.2	38,049	30.7	6325	5.1
East Midlands	11,197	7852	70.1	2932	26.2	413	3.7
West Midlands	13,345	8610	64.5	4067	30.5	668	5.0
East of England	13,949	8623	61.8	4585	32.9	741	5.3
London	12,698	6534	51.5	5028	39.6	1136	9.0
South East	20,142	13,169	65.4	6035	30.0	938	4.7
South West	13,938	9846	70.6	3643	26.1	449	3.2
Rurality[c]							
Urban	96,875	60,836	62.8	30,717	31.7	5322	5.5
Rural	27,071	18,759	69.3	7310	27.0	1002	3.7

SD: standard deviation; GI: gastrointestinal; ED: emergency department; IMD: index of multiple deprivation.
[a]Comorbidity score based on the Deyo modification of the Charlson comorbidity score with the points for malignant disease deducted.
[b]Total number of ED visits in the last year of life excluding the last 30 days.
[c]Rural – settlements with populations ⩾10,000; urban – settlements with populations <10,000.

Table 2. Analysis of factors associated with multiple ED visits by patients with cancer in the last 30 days of life (n = 124,030).

Variables	OR	95% CI	AOR	95% CI
Age in years				
<65	1.00	–	–	–
65–74	**0.86**	**0.80 – 0.92**	**0.85**	**0.79 – 0.91**
75–84	**0.71**	**0.66 – 0.76**	**0.70**	**0.65 – 0.75**
85+	**0.62**	**0.57 – 0.67**	**0.65**	**0.59 – 0.70**
Gender				
Female	1.00	–	–	–
Male	**1.30**	**1.23 – 1.36**	**1.26**	**1.19 – 1.34**
Ethnicity				
White	1.00	–	–	–
Asian	**2.25**	**1.93 – 2.62**	**1.49**	**1.27 – 1.74**
Black	**2.00**	**1.67 – 2.38**	**1.21**	**1.01 – 1.46**
Other	**1.49**	**1.21 – 1.82**	1.10	0.89 – 1.35
Cancer type				
Lung	**1.93**	**1.73 – 2.15**	**1.74**	**1.56 – 1.95**
Breast	**1.33**	**1.16 – 1.53**	**1.49**	**1.29 – 1.73**
Colorectal	1.00	–	–	–
Head and neck	**2.01**	**1.69 – 2.40**	**1.67**	**1.40 – 2.00**
Haematology	**1.44**	**1.26 – 1.64**	**1.32**	**1.15 – 1.51**
Upper GI (inc oesophagus and stomach)	1.45	1.28 – 1.65	1.37	1.21 – 1.56
Gynaecological	1.10	0.93 – 1.29	**1.19**	**1.01 – 1.41**
Prostate	**1.33**	**1.15 – 1.52**	**1.21**	**1.05 – 1.40**
Urinary tract (inc kidney)	**1.20**	**1.03 – 1.39**	1.09	0.94 – 1.27
Hepatobiliary	**1.45**	**1.26 – 1.64**	**1.20**	**1.01 – 1.44**
Pancreas	**1.39**	**1.15 – 1.52**	**1.34**	**1.16 – 1.56**
Other	**1.39**	**1.23 – 1.56**	**1.33**	**1.18 – 1.50**

(Continued)

Table 2. (Continued)

Variables	OR	95% CI	AOR	95% CI
Comorbidity score[a]				
0	1.00	–	–	–
1	**1.38**	**1.30 – 1.47**	**1.31**	**1.23 – 1.39**
2+	**1.63**	**1.53 – 1.73**	**1.53**	**1.43 – 1.63**
Previous ED usage[b]				
0	1.00	–	–	–
1	1.02	0.96 – 1.09	0.97	0.90 – 1.04
2	**1.14**	**1.06 – 1.23**	0.99	0.92 – 1.07
3	**1.33**	**1.21 – 1.46**	1.07	0.98 – 1.18
4	**1.46**	**1.30 – 1.64**	**1.13**	**1.00 – 1.27**
5	**1.71**	**1.48 – 1.97**	**1.28**	**1.10 – 1.48**
6	**2.04**	**1.71 – 2.44**	**1.48**	**1.24 – 1.78**
7+	**2.71**	**2.37 – 3.09**	**1.81**	**1.58 – 2.07**
Socio-economic status (IMD quintile)				
5 – least deprived	1.00	–	–	–
4	1.05	0.96 – 1.14	1.03	0.94 – 1.12
3	**1.09**	**1.01 – 1.19**	**1.03**	**0.94 – 1.12**
2	**1.36**	**1.25 – 1.48**	**1.12**	**1.03 – 1.23**
1 – most deprived	**1.54**	**1.42 – 1.67**	**1.19**	**1.09 – 1.30**
Region				
London	1.00	–	–	–
North East	**0.61**	**0.54 – 0.68**	**0.66**	**0.58 – 0.75**
North West	**0.62**	**0.57 – 0.68**	**0.68**	**0.62 – 0.75**
Yorkshire and Humberside	**0.42**	**0.38 – 0.46**	**0.48**	**0.43 – 0.54**
East Midlands	**0.39**	**0.35 – 0.44**	**0.47**	**0.41 – 0.53**
West Midlands	**0.54**	**0.49 – 0.59**	**0.62**	**0.56 – 0.68**
East of England	**0.57**	**0.52 – 0.63**	**0.72**	**0.65 – 0.80**
South East	**0.50**	**0.45 – 0.54**	**0.62**	**0.56 – 0.68**
South West	**0.34**	**0.30 – 0.38**	**0.43**	**0.38 – 0.49**
Rurality[c]				
Rural	1.00	–	1.00	–
Urban	**1.52**	**1.41 – 1.61**	**1.18**	**1.10 – 1.28**

OR: odds ratio; AOR: adjusted odds ratio; CI: confidence interval; GI: gastrointestinal; ED: emergency department; IMD: index of multiple deprivation.
Figures in bold represent significant findings ($p < 0.01$).
[a]Comorbidity score based on the Deyo modification of the Charlson comorbidity score with the points for malignant disease deducted.
[b]Total number of ED visits in the last year of life, excluding the last 30 days.
[c]Rural – settlements with populations <10,000; urban – settlements with populations ⩾10,000.

and demographic factors. A theoretical model illustrating the relationship and potential interaction between factors has been constructed from the findings (Figure 3).

Our finding of a dose–response relationship between patients' prior ED use and their ED visits in the last month of life has not been previously reported in this population group. In prior work, we have shown that patients receiving palliative care are less likely to visit the ED multiple times in the last month of life.[22] Furthermore, this reduction in odds appears to be greater when palliative care services are provided earlier in a patients' course of illness.[41–43] Yet, despite these findings, many referrals to palliative care still occur late and prompts that encourage earlier engagement are desirable.[44] Multiple presentations to the ED could be used as a trigger for additional support services and may be a more effective method of identifying individuals at increased risk of overly aggressive end-of-life care than screening of multiple socio-demographic and/or clinical factors.[44]

Our finding that patients with greater comorbidity are more likely to attend the ED multiple times is important. With the anticipated effects of population growth and ageing, the future average cancer patient will be older and likely to have ⩾1 comorbidities.[45] With fewer hospital generalists and an overall trend towards increasing physician specialisation, collaboration between healthcare

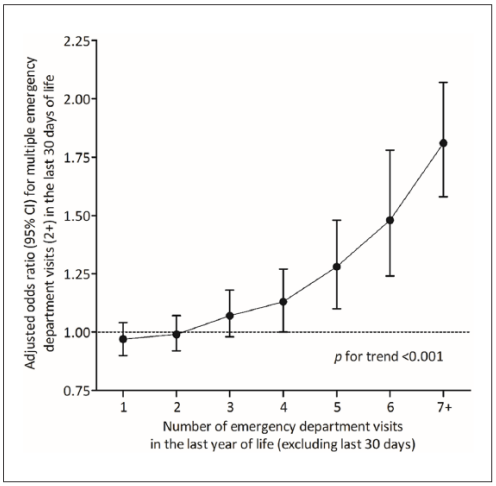

Figure 2. Relationship between cancer patients' prior ED attendance and odds of multiple ED visits in the last 30 days of life.

professionals is increasingly required when managing patients with multiple conditions.[46,47] In order to deliver high-quality care to older more complex cancer patients, healthcare providers need to address the many well-documented challenges associated with care coordination. Such challenges include the following: developing computer systems for effective communication and information sharing between services; providing timely and adequate information to patients and their caregivers; and ensuring sufficient staffing and time.[48,49]

We also found an association between multiple ED visits and a diagnosis of lung or head and neck cancer. The relationship between cancer type and use of acute healthcare services is often attributed to the pattern of disease spread and/or typical profile of symptoms seen with certain malignancies.[50,51] For example, patients with head and neck cancer are at risk of complications that can compromise their airway. Our finding that patients with lung cancer have increased odds of multiple ED visits is consistent with previously published research[18,21,52,53] and alludes to breathlessness being a particularly difficult symptom to manage. Traditional approaches towards managing breathlessness often focus on symptom relief, which although ideal, is more often than not unrealistic, especially for patients with incurable disease. In a recently published randomised controlled trial, Higginson et al.[54] evaluated a breathlessness support service against usual care for 105 adults with refractory breathlessness and advanced disease (including cancer). The primary aim of the intervention was to help patients cope with or 'master' their breathlessness rather than improve overall breathlessness severity scores. This novel approach to symptom management may be one way of reducing end-of-life acute hospital service use secondary to breathlessness, although further evaluation is required.

We found that men, younger patients, Asian and Black ethnic minority groups, and persons of lower socio-economic status were more likely to visit the ED multiple times in the last month of life. These findings, reported for the first time in a UK population, support previously published studies from the United States and Canada and highlight the global extent of socio-demographic inequalities at the end of life.[18,52,55] Previous studies have explored whether this variation could be due to differences in patients' understanding of their disease and prognosis or different preferences for end-of-life care across patient groups.[56–58] While these studies have identified some important differences, the findings are unlikely to explain all the variation found. Further research aimed at understanding *why* such inequalities exist is urgently required.

Our study found a significant area effect for London residents, even after controlling for rurality, suggesting that healthcare service factors, not just clinical need, are important in determining patients' ED use at the end of life. A number of recently published studies have reported evidence of an association between increased use of community services and reduced odds of end-of-life ED visits, hospital admissions and death in hospital.[43,59,60] Despite these findings, recent austerity measures have led to reductions in many community healthcare services across England. The structure of healthcare services is especially important to consider, as unlike many other factors such as patient demographics, it represents a modifiable component of care. To help inform future healthcare planning and policy, further research investigating the relationship between end-of-life ED visits and patients' use of community services is required.

Strengths and limitations

One of the main strengths of our study is the use of patient-level population data to investigate end-of-life ED visits by patients with cancer. ED visits do, however, represent only one indicator of end-of-life care quality and as such our findings should be considered alongside other quality measures such as patients' receipt of chemotherapy, use of hospice services and days spent in hospital or intensive care towards the end of life.[15]

Analysis of routinely collected data can be limited by the type of variables collected and the quality of data coding. ONS mortality data go through stringent quality assessments prior to becoming available which along with the use of automated coding software help maintain consistency and overall data quality.[61] Recording of the underlying cause of death is, however, based on information obtained from a patient's death certificate. Previous studies investigating

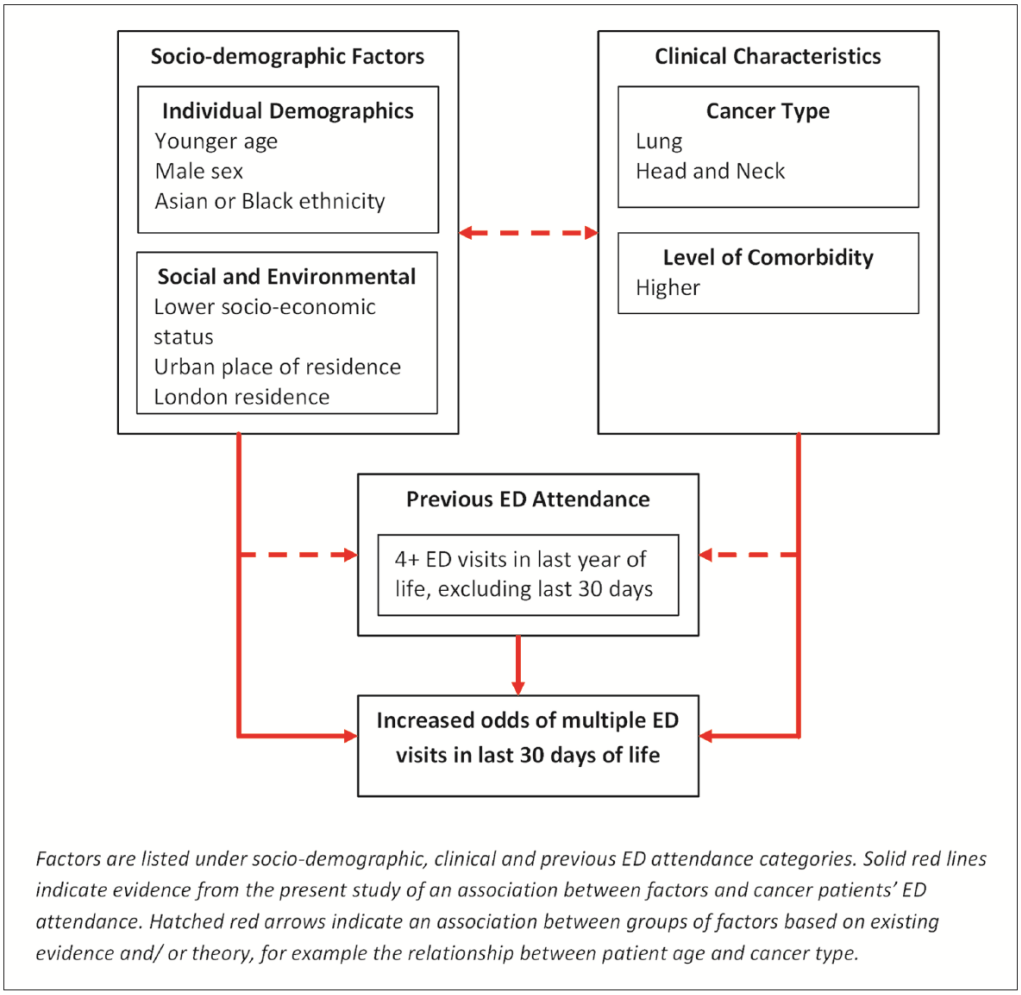

Figure 3. Theoretical model illustrating the relationship between factors and ED visits by patients with cancer in the last 30 days of life.

death certificate completion have reported high levels of inaccuracy.[62] More recent evidence suggests that this has improved and that deaths from cancer are more accurately reported than deaths from other conditions.[63,64] We were not able to explore cause of death from the HES database. It is likely that our cohort included some patients whose cause of death was inaccurate; however, any such errors are not believed to have influenced our overall findings.

The HES Accident & Emergency dataset contained few clinical variables and many were unsuitable for analysis due to high levels of missing or invalid data (including the variable 'reason for ED visit'). There was also a lack of variables relating to patients' use of community services such as palliative care. With analysis of routinely collected data becoming increasingly common in healthcare research, addressing the validity and reliability of clinically coded variables is an important next step towards maximising the value of such resources.

Finally, population trends can only ever be a guide for the care that any one individual will require at the end of life. In many situations, the ED is the most appropriate setting for urgent care needs to be managed and the importance of providing individualised patient-centered care should not be overlooked.

Conclusion

Patients' with a greater number of prior ED visits, more comorbidities and diagnosis of lung or head and neck cancer are more likely to visit the ED multiple times in the last month of life. Previously reported socio-demographic factors (men, younger age, Black ethnicity, low socio-economic status) are also confirmed for the first time in a UK population. Flagging cancer patients who experience recurrent ED visits could support earlier identification of individuals at high risk of overly aggressive end-of-life care. This may be a more effective and efficient approach than screening of multiple socio-demographic and/or clinical factors.

Acknowledgements

CI: Higginson. Grant leads: Higginson, McCrone, Normand, Lawlor, Meier and Morrison. Project coordinator/PI: Daveson. Study arm PIs: Pantilat, Selman, Normand, Ryan, McQuillan, Morrison and Daveson. The authors thank all collaborators and advisors including service-users. BuildCARE members: Emma Bennett, Francesca Cooper, Barbara A Daveson, Susanne de Wolf-Linder, Mendwas Dzingina, Clare Ellis-Smith, Catherine J Evans, Taja Ferguson, Lesley A Henson, Irene J Higginson, Bridget Johnston, Paramjote Kaler, Pauline Kane, Peter Lawlor, Paul McCrone, Regina McQuillan, Diane Meier, Sean Morrison, Fliss E Murtagh, Charles Normand, Caty Pannell, Steve Pantilat, Ana Reison, Karen Ryan, Lucy Selman, Melinda Smith, Katy Tobin, Rowena Vohora and Gao Wei. All data were supplied by the Health & Social Care Information Centre. Copyright© 2013, re-used with the permission of the Health & Social Care Information Centre. All rights reserved.

Author contribution

Lesley A Henson and Wei Gao, with critical revisions from Irene J Higginson, contributed to conception and design, and manuscript writing. Lesley A Henson, supervised by Wei Gao, contributed to checking and cleaning of data. All authors contributed to data analysis and interpretation. All authors made final approval of manuscript.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship and/or publication of this article: This study was conducted as part of the project BuildCARE; supported by Cicely Saunders International (CSI) and The Atlantic Philanthropies, led by King's College London, Cicely Saunders Institute, Department of Palliative Care, Policy & Rehabilitation, UK. The authors acknowledge the additional support received from the Collaboration for Leadership in Applied Health Research and Care (CLAHRC) South London, National Institute for Health Research (NIHR). The CLAHRC is a partnership between King's Health Partners, St George's University London and St George's Healthcare NHS Trust. The funders had no role in the study design, data collection and analysis, decision to publish or preparation of the manuscript.

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Chapter 6 - ‘I’ll be in a Safe Place’: A Qualitative Study of the Decisions Taken by People with Advanced Cancer to Seek Emergency Department Care [PUBLICATION 4]

BMJ Open

'I'll be in a safe place': a qualitative study of the decisions taken by people with advanced cancer to seek emergency department care

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To cite: Henson LA, Higginson IJ, Daveson BA, *et al*. 'I'll be in a safe place': a qualitative study of the decisions taken by people with advanced cancer to seek emergency department care. *BMJ Open* 2016;**6**:e012134. doi:10.1136/bmjopen-2016-012134

► Prepublication history and additional material is available. To view please visit the journal (http://dx.doi.org/10.1136/bmjopen-2016-012134).

Received 1 April 2016
Revised 1 July 2016
Accepted 8 September 2016

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ABSTRACT

Objective: To explore the decisions of people with advanced cancer and their caregivers to seek emergency department (ED) care, and understand the issues that influence the decision-making process.

Design: Cross-sectional qualitative study incorporating semistructured patient and caregiver interviews.

Methods: Between December 2014 and July 2015, semistructured interviews were conducted with 18 people with advanced cancer, all of whom had recently attended the ED of a large university teaching hospital located in south-east London; and six of their caregivers. Interviews were audio recorded, transcribed verbatim and analysed using a constant comparative approach. Padgett and Brodsky's modified version of the 'Behavioral Model of Health Services Use' was used as a framework to guide the study.

Results: Issues influencing the decision-making process included: (1) disease-related anxiety—those with greater anxiety related to their cancer diagnosis interpreted their symptoms as more severe and/or requiring immediate attention; (2) prior patterns of health-seeking behaviour—at times of crisis participants defaulted to previously used services; (3) feelings of safety and familiarity with the hospital setting—many felt reassured by the presence of healthcare professionals and monitoring of their condition; and, (4) difficulties accessing community healthcare services—especially urgently and/or out-of-hours.

Conclusions: These data provide healthcare professionals and policymakers with a greater understanding of how systems of care may be developed to help reduce ED visits by people with advanced cancer. In particular, our findings suggest that the number of ED visits could be reduced with greater end-of-life symptom support and education, earlier collaboration between oncology and palliative care, and with increased access to community healthcare services.

Strengths and limitations of this study

- Understanding what influences people with advanced cancer to seek emergency department (ED) care is key to developing initiatives aimed at reducing high attendance; to date, however, such evidence is limited. To address this issue we conducted a qualitative interview study exploring the decision-making process of people with advanced cancer and their caregivers to seek ED care.
- Semistructured in-depth interviews were conducted with 18 people with advanced cancer, all of whom had recently attended the ED of a large university teaching hospital located in south-east London; and six of their caregivers.
- We adopted a maximum variation (heterogeneity) sampling strategy to identify people with a range of characteristics and capture potentially richer and more diverse data relevant to the research question.
- Our study interviewed people who decided to seek ED care. The decision-making process of those who used alternative services was not explored and is a limitation of this research.

BACKGROUND

A large proportion of all healthcare expenditure in developed countries is consumed by care for those in the last year of life; in the UK this is estimated at 10–20% of the National Health Service (NHS) budget, while in the USA it accounts for as much as 30% of the Medicare budget.[1 2] This pattern of spending is especially pronounced for people with cancer. Despite the cancer trajectory being highly predictable, costs escalate at an exponential rate up to the time of death,[3] with the additional costs almost entirely attributable to an increased use of acute hospital services, in particular emergency department (ED) visits and unplanned hospital admissions.[1 4]

The increased use of acute hospital services towards the end-of-life would not be such a concern if it improved outcomes for patients with cancer and their families.

However, evidence suggests this is not the case. Instead, prolonged hospital admissions and/or multiple ED visits in the last month of life are associated with greater physical distress, overall dissatisfaction with care and more than a threefold increase in the likelihood of psychiatric illness among bereaved relatives.[5–7] Furthermore, for the majority of people with cancer, acute hospital care is diametrically opposed to their stated preferences for end-of-life care.[8] Most (64–84%) people with cancer prefer to be cared for and die at home,[9] surrounded by their loved ones and free from the stressful environment of an acute hospital.[9–12]

Reducing patients with cancer use of acute hospital services towards the end-of-life therefore provides an opportunity to improve overall care quality and reduce healthcare costs. These clear individual and societal benefits have motivated policymakers to introduce measures to minimise acute hospitalisations. To date, however, the impact of such initiatives has been limited; instead, the number of people with cancer experiencing multiple ED visits and/ or with prolonged hospital admissions towards the end-of-life has risen.[13 14] In England, most ED visits represent self-presentations.[15] Hence, if future initiatives are to be successful, a more comprehensive understanding of *why* people with cancer choose ED care is required. Only then will it be possible to devise a system of end-of-life care services that can effectively serve the needs and preferences of people with cancer and their families.

Most of the existing research on end-of-life ED use by people with cancer has focused on quantifying attendance and/or identifying factors associated with an increased risk of multiple visits in the last month of life.[16–18] While these studies have identified a number of sociodemographic, environmental and clinical risk factors (eg, sex, age, ethnicity, socioeconomic status and type of cancer), evidence for *why* people with cancer decide to attend the ED is limited.[19 20] In order to address this issue and help guide development of future healthcare services, we conducted the following qualitative study. The aim of our study was to explore the decisions of people with advanced cancer and their caregivers to seek ED care, and understand the issues that influence the decision-making process.

METHODS

This study is reported following the consolidated criteria for reporting qualitative studies (COREQ).[21]

Theoretical framework

Many previous studies have explored patients' use of healthcare services[22–25] and extant models of health-seeking behaviour can be useful to guide future research and investigation. The most widely acknowledged theory of healthcare usage is the 'Behavioral Model of Health Services Use' developed by Andersen in 1968 and subsequently published with Newman in 1973.[22] Although initially developed to explain non-discriminative healthcare use among the general population, the model has since been applied to a variety of services and populations.[26] It has not, however, been used to examine the uptake of healthcare services by people with advanced cancer or at the end-of-life. In 1992, Padgett and Brodsky[27] modified the model, specifically to explain non-urgent ED use. In this adapted version, three stages of decision-making are identified: (1) problem recognition; (2) decision to seek medical care; and, (3) decision to use the ED. Predisposing, enabling and need-based factors—as per Andersen and Newman's original model—are proposed to influence each of these three stages.[27] This modified version of the model was used as a framework for our study. The model's utility when applied to a different population group—people with advanced cancer—was also tested.

Setting

A large university teaching hospital in south-east London, serving an ethnically, socially and economically diverse urban population of approximately two million. The hospital's ED sees over 120 000 patients each year—about 350 patients a day.[28]

Participants

Participants were adults (≥18 years) with advanced cancer who had recently attended, from their private residence, the hospital's ED; and where applicable their main caregiver (see box 1).

Box 1 Study eligibility criteria

Inclusion criteria: patients
- Adults (≥18 years).
- Diagnosed with advanced cancer by a qualified healthcare professional involved in the patient's care. Advanced cancer defined as cancer that has invaded surrounding body tissues and/or metastasised, and is not curable and is life-threatening.
- Assessed as having a prognosis of weeks to short months by a qualified healthcare professional involved in the patient's care.
- Attended, from their private residence, the emergency department (ED), within 2 weeks of screening for the study.

Inclusion criteria: caregivers
- Adults (≥18 years).
- Identified as their caregiver by an eligible patient recruited to the study. Caregiver defined as an unpaid family member/close friend involved in caring for the patient's physical, emotional and/or practical needs.

Exclusion criteria: patients and caregivers
- Participants incapable of providing informed consent.
- Patients attending the ED from nursing homes, care homes or other institutionalised care settings.
- Patients brought to the ED by representatives of Her Majesty's Prison Service and under their supervision.
- Participants whose clinical team considers them to be too unwell and/or distressed to participate in the study.

Recruitment of patients was through the hospital's palliative care and acute oncology teams. Between 16 December 2014 and 31 July 2015 both teams screened all new referrals against the study's eligibility criteria. The acute oncology team also screened all ED discharges for people with advanced cancer who attended the ED but were not admitted. Any eligible patients identified were first approached by a clinical member of the team who provided them with a leaflet about the study and assessed their interest in participating (patients already discharged were phoned at home). Those who expressed interest in the study were then followed-up by a member of the research team, either face-to-face or via the telephone.

Recruitment to research studies can be especially challenging in vulnerable population groups such as those with advanced diseases. Issues such as gate keeping, high symptom burden and a rapidly changing clinical picture often result in poor recruitment and/or high attrition rates.[29] To help overcome some of these challenges the research and clinical teams collaborated closely during the study period, with face-to-face meetings at least twice weekly. This enabled prompt follow-up of potential participants, most of whom were contacted by the research team within 24 hours of them expressing interest in the study. Additional strategies to reduce attrition included flexibility around the interview setting and timing, as well as the option to conduct joint patient and caregiver interviews if preferred.

We adopted a maximum variation (heterogeneity) sampling strategy to identify people with a range of characteristics and capture potentially richer and more diverse data relevant to the research question.[30] Sampling criteria were based on the findings of a recently conducted systematic review exploring factors associated with ED attendance by patients with cancer in the last month of life, and were: sex; age; ethnicity; socioeconomic status; type of cancer; and use of palliative care services.[18]

Caregivers were identified through patients enrolled to the study, all of whom were asked if they had a family member/close friend that helped care for any of their physical, emotional and/or practical needs. For patients who identified a caregiver, permission was sought for a member of the research team to approach the caregiver regarding study participation.

Recruitment of both patients and caregivers continued until data saturation was achieved. Specifically, this was the point when we were confident that the emerging themes and constructs appeared to be fully represented by the data collected. Additional interviews did not result in a greater depth of understanding or the generation of new themes and/or constructs.[31]

Interviews

Each participant consented to a one off semistructured interview with researcher LH (palliative care physician (MBBS, MRCP) and PhD clinical training fellow; female). All interviews were audio recorded and field notes were made during or immediately after each interview. At the request of participants, caregiver interviews were conducted jointly with patients apart from in one case where the caregiver interview occurred immediately following the patient interview. During the consenting process LH explained that she was working with the palliative care or acute oncology team to conduct a study about people's decisions to seek ED care. No further information about the research team was offered.

During interviews participants were asked to describe the most recent time that they, or their family member/close friend, attended the ED and the issues that influenced their decision-making process. In order to enhance the consistency and completeness of data collected across cases, topic guides were developed (based on the study's theoretical framework[27]), piloted and used during interviews (see online supplementary file 1—patient interview topic guide; online supplementary file 2—caregiver interview topic guide). Participants were encouraged to talk in-depth about their thought processes with prompts used to elicit further information when required.

Analysis

Interviews were anonymised, transcribed verbatim and analysed using a constant comparative approach.[32] Analysis began with open coding of the transcript where meaningful words, phrases and statements were identified, followed by more detailed axial coding as items emerged. These items were then grouped into themes which became further refined as the analysis continued. Differences and similarities were explored within and across interviews. Where new themes emerged, earlier interviews were reanalysed to consider further and/or alternative meaning, with particular attention paid to non-confirmatory/divergent cases.

All interview transcripts were analysed by researcher LH. To address issues of analytical rigour, credibility and trustworthiness, a selection of interviews were also analysed by researchers CE-S and JK, and then reviewed with LH. Where coding differed, areas were reconsidered and discussed until consensus was reached regarding interpretation and overall meaning.

RESULTS

Characteristics of participants

Seven hundred and thirty-one patients were screened for the study, of whom 67 met the eligibility criteria and were approached regarding participation. Twenty-two patients declined to participate citing reasons that included 'not interested' and 'didn't feel up to it'. A further 22 patients became too unwell or died in the short time period between being approached about the study and an interview being arranged. The final five patients were excluded for other reasons, including closure of a hospital ward because of a Norovirus

outbreak. A total of 18 patients were recruited to the study (figure 1).

Among the 18 patients recruited, 10 identified a family member/close friend as their main caregiver, with one patient identifying two family members. Permission was given for eight of these individuals to be approached about the study. One caregiver declined to participate stating 'they didn't have enough time' and one was unable to consent; the remaining six were enrolled to the study (figure 1).

No participants withdrew from the study, however two interviews ended early. In one case (ED03), after 27 min, the patient felt unwell and unable to continue with the interview. In the second case (ED16), the patient found the study questions frustrating, in particular the level of detail being asked, and requested to stop after 13 min. Eighteen of the 24 interviews were conducted in hospital, 5 in participants' homes and 1 in the hospital's Macmillan Information and Support Centre. No other persons apart from those involved in the study were present during the interview process. Interviews lasted an average of 31 min (range 13–57). The mean number of days between the patient's interview and death was 90 (range 7–252) (Five patients remained alive as of the 16 February 2016).

Characteristics of the 18 patient participants are presented in table 1.

Accounts of the decision-making process

During each interview participants narrated their own unique account of the events leading up to their ED visit. In keeping with the study's theoretical framework,[27] participants' overall decision-making was composed of three key stages: (1) problem recognition; (2) decision to seek medical care; and, (3) decision to use the ED. For some participants these decision-making stages occurred quickly (within minutes), while for others one was deliberated to a greater extent than the other. For a few participants the initial 'problem recognition' and 'decision to seek medical care' stages were so intuitive that they struggled to recognise any decision-making at this time. For example, patient ED16 began his interview by describing back pain he had experienced in the days leading up to his ED visit. When asked why he decided to seek medical care, he struggled to describe his decision-making further, instead repeating that pain was the reason he sought help.

> ED16 [patient]: Well the pain.
> Researcher: Okay, but you'd had it [the pain] for a few days?
> ED16: Yeah.
> Researcher: So what changed?
> ED16: Well the pain.

Later during the interview ED16 was able to elaborate further. He explained that over a period of days his pain got progressively worse to the extent that on the morning of his ED visit he had struggled to get out of bed. It was this feature—the pain limiting his mobility—that triggered his decision to seek medical care.

Each of the decision-making stages, and the issues that influenced them, are presented below.

Stage 1: problem recognition

All participants described physical problems during their interviews with a wide range of symptoms reported, including pain, fevers, breathlessness and seizures (table 1). While most reported these physical symptoms as central to their decision to seek medical care, it became apparent that most experienced symptoms at many other points in time for which they did not decide to seek help. Instead it was participants' perception, or interpretation, of their symptom(s)—rather than the symptom per se—which appeared to influence their decision-making.

Symptom interpretation varied considerably between participants. Some interpreted their symptom(s) as severe and felt compelled to seek medical care as soon as possible. Others perceived their symptoms as mild, or to be expected, and consequently did not decide to seek medical care until another event triggered them to seek help. Three concepts emerged as influencing participants' symptom perception/interpretation: (1) anxiety relating to their underlying cancer diagnosis; (2) prior symptom experiences; and (3) education and knowledge.

Anxiety relating to underlying cancer diagnosis

A number of participants conveyed narratives explaining how their diagnosis of cancer felt like a 'death sentence' and was 'always on their mind'. Any new symptom experienced would be interpreted within this context. For example, patient ED02, a woman with colorectal cancer, described how she immediately thought her cancer was progressing when she developed pain.

> ED02 [patient]: it's always going to trigger (Researcher: Okay) is this thing growing? Is this get…is it getting out of hand you know? (Researcher: Okay) You know, what is, what is going to happen?

Two patient characteristics appeared to influence participants' anxiety of their cancer: age; and religious or spiritual beliefs. Compared to younger patients, older patients tended to describe less anxiety related to their cancer diagnosis and subsequently were less likely to perceive a new symptom as always being cancer related.

> Researcher: So when you fell onto the floor, that [cancer] wasn't something going through your mind?
>
> ED06 [patient]: When, when?
>
> Researcher: When you slipped from the chair?

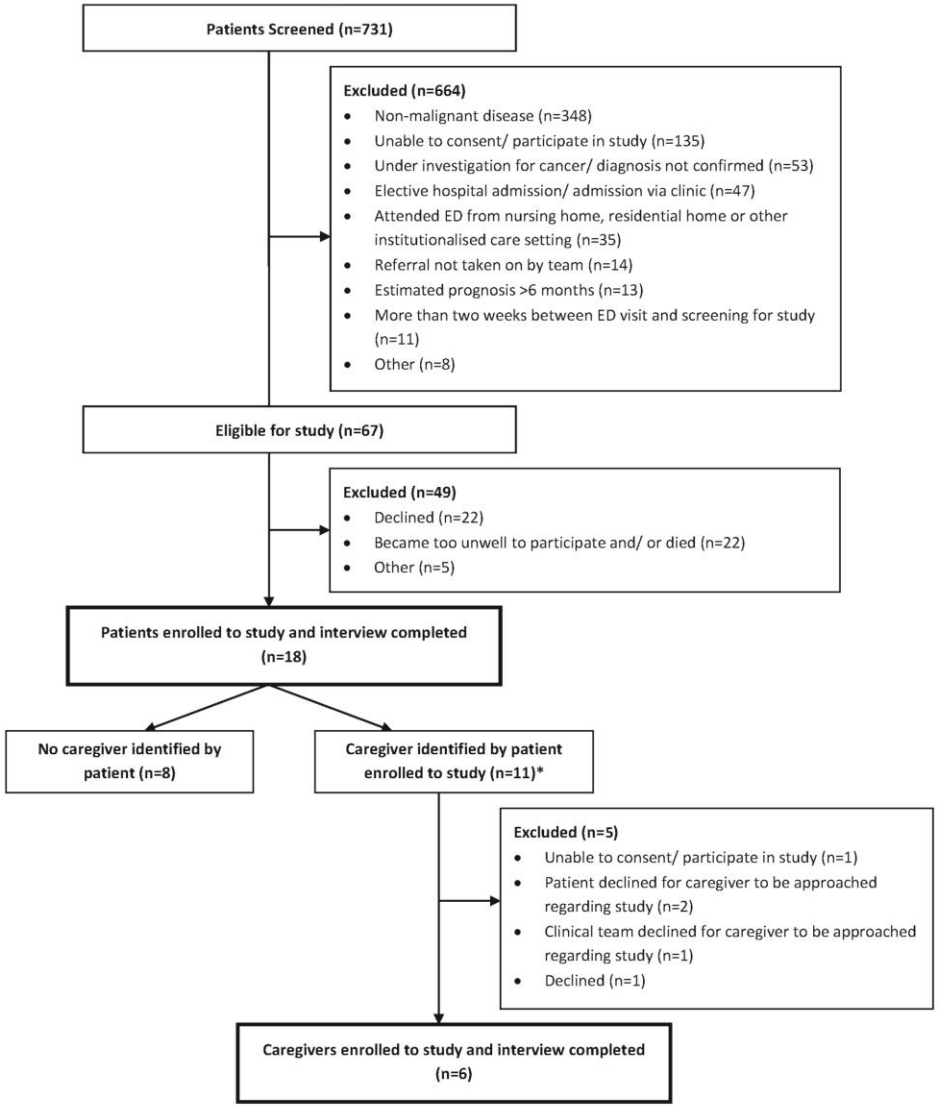

Figure 1 Flow diagram of patient and caregiver recruitment. *One patient identified two family members. ED, emergency department.

ED06: Oh! Good God no! I was looking at the bloody football score [laughs].

Participants' with religious or spiritual beliefs described how their faith helped them cope with their cancer diagnosis and any symptoms they experienced.

ED18 [patient]: …my faith is very strong in in what I believe, and, that really takes care of a lot of the…the burden if I should say, (Researcher: Okay) you know. When…when I get to a state where I get like a bit of a wimp, I pray.

Prior symptom experience

Participants' recollections of previously experienced symptoms also influenced how they interpreted their situation. Many considered a new symptom as 'severe' and/or 'urgent' if it was similar or related to symptoms they had experienced around the time of their cancer

Table 1 Characteristics of patient participants

Type of cancer	N	Sex (male/female)	Age in years (mean (range))	Ethnicity (white British/other)	Socioeconomic status* (1–2/3–5)	Under community palliative care prior to ED visit (yes/no)	Reasons for ED attendance
Lung	4	3/1	70 (45–86)	3/1	3/1	1/3	Focal seizures; malaise; pain; breathlessness and malaise.
Haematological malignancies	4	2/2	75 (59–90)	4/0	4/0	1/3	Pain; rectal bleeding; fever; fever.
Prostate, gynaecological and urinary tract	4	2/2	72 (55–88)	3/1	4/0	2/2	Fall; pain; facial weakness and malaise; haematuria.
Gastrointestinal and hepatocellular	3	1/2	59 (42–68)	1/2	2/1	1/2	Pain; pain fever and cough; fever.
Other	3	1/2	37 (19–47)	0/3	1/2	0/3	Pain; facial numbness and headache; fever and pain.

*Socioeconomic status derived from index of multiple deprivation (IMD) quintiles (1st—most deprived; 5th—least deprived). The IMD is an area based measure of deprivation that uses Lower Super Output Area geography to compare deprivation between neighbourhoods in England.
ED, emergency department.

diagnosis. This was illustrated by patient ED10 who explained how he had been diagnosed with metastatic lung cancer after having a grand-mal seizure. Despite experiencing many other symptoms since then, ED10 had not had another seizure until the week of his interview when he developed a partial seizure of his arm and decided to immediately seek help. ED10 described his thoughts at this time:

> ED10 [patient]: That decision came because of the past experience. So we know its brain. (Researcher: Okay) So our fear was it's—it may have grown bigger and the pressure could be you know imminent danger.

Education and knowledge

Several patients had received advice from healthcare professionals regarding specific symptoms. This education and knowledge influenced their interpretation of how important certain symptoms were and whether or not they decided to seek help.

> ED12 [patient]: …the reason I came in is because erm, I've got cancer, and erm, I was erm being looked after at XX Hospital team and they told me, erm if I've got a temperature above erm I think it's 37 point something then I should go to my nearest A&E. I did have a temperature of 38 point. I called them and the nurse said to me I should make my way here just in-case I had an infection.

The levels of anxiety relating to having a diagnosis of cancer was variable across individuals, as above, and did not appear to differ between those who were and were not receiving community palliative care. Participants who received symptom advice/information from their palliative care team did describe less anxiety regarding new symptoms and several also reported seeking alternative sources of help before deciding to attend the ED.

Stage 2: decision to seek medical care

For those who interpreted their symptom(s) as severe, their decision to seek medical care followed rapidly and was often hard to separate from the initial problem recognition stage. However, for participants who did not seek help immediately and instead accommodated or managed their symptom(s), this second decision to seek medical care appeared to occur later when for some reason they were no longer able to tolerate, or accommodate, their symptom(s). Reasons for why this accommodation broke down included situations where the symptom changed in character, started to interfere with activities of daily living and/or persisted beyond an arbitrary time threshold. Patient ED25, a woman with bladder cancer, explained how despite having experienced multiple previous episodes of cancer-related haematuria, she decided to seek help for the most recent occurrence because the bleeding became increasingly severe and persisted beyond 3 days.

ED25 [patient]: the bleeding just got heavier and heavier and heavier and went on for about four days and didn't abate at all—it just got worse.

In another example, patient ED18, a woman with metastatic breast cancer, described how she had been managing with back pain for several days. However, it was when the pain became so severe that is started to restrict her movements that she decided she needed help.

ED18 [patient]: So it's like certain movements I couldn't even do. (Researcher: Okay) Yeah, it like just trapped me there.

Sanctioning by family and/or healthcare professionals was also described. During one interview, patient ED12 explained how her family would encourage her to seek medical care for symptoms that she felt she was coping with. At times their insistence was so great it would lead to her seeking medical care.

ED12 [patient]: Well they put pressure on me and sometimes to shut them up [laughs], just to shut them up, I would call the nurse, yes they [family]…they…they influenced me to call the nurse then yeah. To keep them [family] happy you know and to stop nagging me.

Stage 3: decision to use the ED

Once participants had decided to seek medical care, their decision to use the ED was explored. Four concepts emerged as key to this stage of decision-making: (1) availability and ease of access; (2) hospital facilities and environment; (3) trust and healthcare provider continuity; and, (4) ability to abdicate responsibility.

Availability and ease of access

Both the availability of healthcare services and their ease of access were important to participants when deciding where to seek help. Participants preferred services where they could receive care quickly and with little stress or inconvenience. Overly complicated systems were bypassed for more straightforward options, for example, patient ED01 described how he chose to attend the ED over an alternative healthcare service because access to the latter often involved multiple steps and time. By comparison, once he arrived at hospital, healthcare professionals would come to him and the responsibility for identifying and accessing the 'right' care was organised for him.

ED01 [patient]: …they would have to go through someone else to go through someone else (Researcher: Mmm) do you know what…I wouldn't want anything like that. Erm or I might as well just come to hospital in that case (Researcher: Okay) because eventually I'll be in a safe place and they'll come to me.

Trouble accessing appointments, especially those which were urgent and/or out-of-hours, was an important barrier to participants' seeking help from their general practitioner (GP) and often facilitated their decision to instead attend the ED.

ED08 [daughter]: Can't get hold of dad's GP of a weekend. (Researcher: Okay) (ED07 [patient]: No) I can't get hold of my GP in XX [local area of patient] of a weekend so erm (Researcher: Okay) it goes through to XX [out of hours service].

A few participants described contacting other healthcare services prior to attending the ED, in most cases telephoning their oncology nurse specialist or community palliative care team. When probed further about these decisions only one participant described calling because she hoped this would result in some action that could help her avoid attending the ED. The remaining participants reported other reasons for calling their oncology team. One patient explained that he called his oncology team as a courtesy; he had been advised to call them with any new symptoms. Another patient explained how calling the oncology team sometimes expedited the hospital's triage process, stating:

ED22 [patient]: Yes and the advantage of phoning ahead is they sort of expect you, and therefore you might get through a stage quicker.

Community palliative care services were often not called as participants felt they would be unable to help in an emergency situation. Instead community palliative care services were described as being able to help with non-urgent issues and help facilitate communication between services such as their GP and oncology.

In only one case was advice from the patient's GP sought prior to them attending the ED. During this interview, ED17, son of ED16, explained that since his father's cancer diagnosis his GP would always make himself available, even if his schedule was full.

ED17 [son]: He's even gave him an open appointment that if we need to see him we will see him. If the…if the reception says there's not a…a…a space in the normal appointment times, he makes time at the end of the surgery.

This level of GP support meant that both ED16 and ED17 felt they would always seek advice from their GP prior to seeking help elsewhere; ED16 explained that although he thought his father needed to be in hospital he still decided to contact his GP first.

ED17 [son]: He [GP] would come at the end of the surgery……Although to us at the time he needed to be in there [hospital]. (Researcher: Okay) But as I…as I say it's…it's easier going through the GP.

Hospital facilities and environment

When deciding where to seek help from, participants tended to favour care delivered in a hospital over other less acute or community settings. They described feeling comforted by the frequent monitoring of their condition and the presence of healthcare professionals.

> ED19: …Like in the hospitals when you go they give you lots of attention, lots of treat—you are under their eyes, they come and check you, monitoring you.

Several participants also described how the hospital provided facilities and equipment that they considered essential for the management of their symptoms. Many held strong beliefs about the type and level of care their condition required, for example, intravenous antibiotics, which appeared to originate from a combination of their clinical knowledge, previous healthcare experiences and/or an instinctive feeling regarding the treatment they required. None of the participants interviewed identified alternative settings where inpatient care could have been accessed. Patient ED10 explained how his decision to call 999 was based on both his previous symptom experiences as well as his knowledge of his cancer.

> ED10 [patient]: …Because I know what's going on. I have a slight idea, I have the fear that this could be this, because we've done a lot of research, (Researcher: Okay) on how things work. And now I'm on a few forums as well and so I know cases where—what other people have experienced.

In comparison, patient ED04 reported instinctively 'knowing' that her symptoms required hospital care despite not having any specific treatments or tests in mind. She said:

> ED04 [patient]: Well because I knew he [GP] couldn't do anything about it but get me to…to the hospital because of all that, and I knew. He wouldn't—they couldn't have done anything, only getting the ambulance and coming here.

Trust and healthcare provider continuity

During interviews several participants spent time talking about their relationship with the hospital, which often began around the time of their cancer diagnosis. Participants described how over months, or even years, of investigations and treatment, relationships with hospital professionals had developed. For many this process had led to them becoming familiar with the hospital and their clinical team. Many held feelings of trust or 'belief' in the care being provided by the hospital.

> ED05 [daughter]: It's…it's nice to come to a place that you're not frightened of. (Researcher: Yeah) You know, that makes you feel good.
>
> ED04 [patient]: That's right you believe in you know, you've got to believe in it.
>
> ED05: Yeah we believe—that's the word mum we believe in XX [hospital] don't we?
>
> ED04: We believe in it—first words are don't take me anywhere (ED05: Yes) but XX [hospital]. (Researcher: Okay) That is true.

In contrast to the hospital relationships that had developed, most participants described rarely seeing their GP during this time. Some stated explicitly that their GP had little or no role in the management of their cancer.

> Researcher: …do you tend to see your GP more now or less now? How do you feel?
>
> ED13 [patient]: Never see him.
>
> ED14 [wife]: Yeah, very rarely.
>
> ED13: Never see GP. Don't see the point.

When it came to seeking help, these relationships influenced participants' decision-making, especially at times of crisis when participants defaulted to services they had previously used and felt safe with. In the majority of cases this ended up being the hospital—only one patient described having a more trusting relationship with their GP than with the hospital.

Abdicate responsibility

When participants decided to attend the ED many also described acute feelings of being unable to cope or manage at home.

> ED25 [patient]: Because my big fear was—would be that, you know…a giant clot is gonna form and I'm gonna be yelling and screaming in somebody's house or restaurant get me to hospital you know.

By seeking help from the hospital participants were enabled—and in many cases expected—to abdicate responsibility for their care to healthcare professionals. The carer of one patient explained how she brought her father to the ED because she had run out of options to care for him at home.

> ED08 [daughter]: Erm, and what am I supposed to do if that happens? I'm not qualified in anything other than just sort of being able to hold him tight (Researcher: Mmm) and cuddle him.

DISCUSSION

This qualitative study provides new findings that help explain *why* and *how* people with advanced cancer decide to seek ED care. We have identified individual's symptom interpretation, their prior patterns of health-seeking behaviour, feelings of safety and familiarity with the hospital setting and difficulties accessing community healthcare services as important issues influencing the decision-making process.

Consistent with our study's theoretical framework, participants described a three-stage process of decision-making. The influence from predisposing, enabling and need-based factors, did however vary from the original framework, as illustrated in figure 2.

Need-based factors were identified as the most important influence on patients' problem recognition (stage 1). In particular, patients' anxiety relating to their underlying cancer diagnosis significantly influenced their symptom perception in terms of meaning and severity. While predisposing factors, such as age, also influenced problem recognition, this effect appeared to act through patients' symptom perception/interpretation. For example, we found older patients were less likely to interpret symptom (s) as a sign of illness and therefore less likely to recognise them as a problem. A number of previous studies have identified variation in patients with cancers' ED attendance based on differing sociodemographic (predisposing) factors.[16–18] Our findings, however, suggest that rather than these factors per se influencing patients' ED use, it is the variation in symptom perception among these groups that ultimately determines the overall differences seen. This mechanism of action is further supported by previous studies that have identified variation in symptom perception by patient sociodemographics, including differences found across social class[33] and ethnicity.[34] Addressing the anxiety and other psychological sequelae commonly experienced by patients with cancer is an important component of high-quality holistic care. Evidence that people experience an increasing sense of vulnerability and/or lack of control prior to seeking emergency hospital care has been reported in similar studies.[19] Integrating interventions to reduce anxiety and/or enhance coping to current end-of-life support services may be one approach towards modifying patient's symptom perception/interpretation. Understanding these decision-making mechanisms is important for clinical practice, especially at a policy level where the findings may be used to inform services delivery and/or intervention development. We suggest that rather than developing policies/interventions that target a particular 'high-risk' patient group, for example, ethnic minority patients or those of lower socioeconomic status, educating patients regarding end-of-life symptoms is likely to be more effective through addressing the issues of symptom interpretation and/or levels of distress. Indeed targeting patients identified as having greater levels of anxiety regarding their symptoms may be more effective and not exclusive to those with specific predisposing factors.

While there was strong evidence for the influence of need-based factors on patients' problem recognition (stage 1), our study did not support enabling factors as also being influential. These were however, important to both subsequent stages of decision-making: decision to seek help (stage 2); and, decision to use the ED (stage 3) (figure 2). In healthcare research enabling factors are arguably the most important to consider since they represent the group of variables most amenable to change. Understanding how this group influences patients' health-seeking behaviour can therefore provide policymakers with better evidence to develop and/or modify existing healthcare structures to improve patient outcomes. Presently, in the UK, one in every two people will be diagnosed with some form of cancer during their

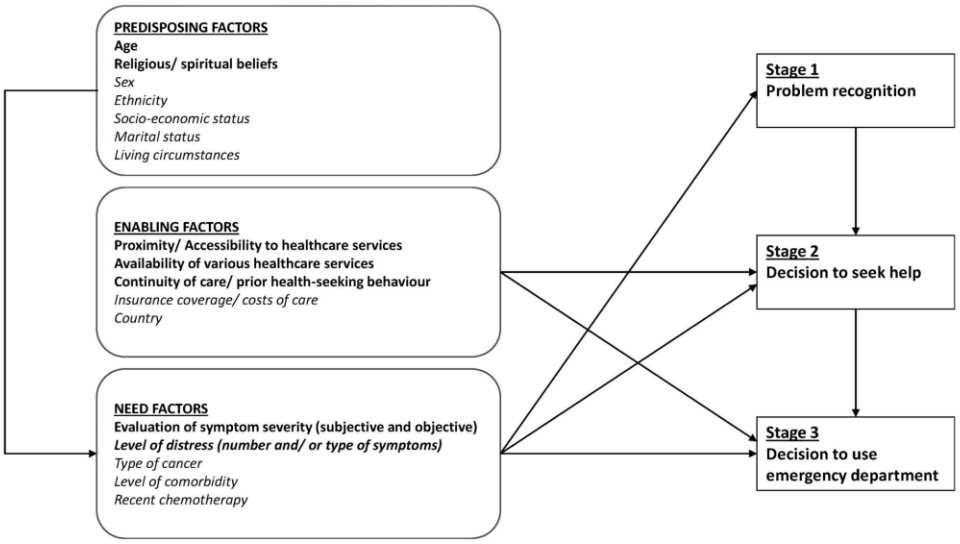

Figure 2 Model of factors influencing advanced cancer patients' emergency department use. Factors in bold indicate those with evidence from current study, factors in italic indicate those identified from previous studies.

lifetime. Despite advances in oncology care and treatment, 50% of those diagnosed will ultimately die from their disease.[35] For these patients, the current model of healthcare delivery is one where as their disease progresses they transition from receiving exclusively oncological care—a predominantly hospital-based specialty, to mostly palliative care—more community-based.[36 37] Implementing this model of transition is, however, challenging. Studies have found that many oncologists are reluctant to refer their patients to palliative care which some perceive as 'an alternative philosophy of care incompatible with cancer therapy' (Schenker *et al*, 2014, pp. e41).[38] Furthermore, inaccurate prognostication often leads to an overestimate of survival,[39] meaning that many transitions to palliative care are often initiated too late in a patients' illness or do not happen at all.[40] During interviews we observed that patients' health-seeking behaviour tended to favour hospital-based care. This preference occurred in part as a result of the extensive hospital contact patients had experienced earlier in their illness, along with very limited GP and community service engagement during this time. Patients require time to become familiar with new services and for their patterns of health-seeking behaviour to change. Studies showing an association between earlier palliative care referral and fewer ED visits at the end-of-life,[41 42] as well as those that show less aggressive end-of-life care with greater community healthcare contact[43] further support these findings. If the time between palliative care referral and patient death is insufficient, patients are likely to continue to use services they are familiar with, especially at times of crisis. New models of healthcare delivery that encourage earlier integration between oncology and palliative care are required to address this issue.

The availability of community healthcare services was also important in patients' decision-making, with several participants describing having 'no alternative' to attending the ED. In a recently published qualitative critical incident study of people with advanced respiratory disease, Karasouli *et al*[19] found that the decisions of participants to seek emergency hospital care were reinforced in those who had experienced difficulty accessing support from community services. While access remains critical, we found that the structure of community services also needs consideration. Our study highlighted key features of the hospital environment described as important to participants, for example, many felt reassured by the presence of healthcare staff to whom they were also able to abdicate responsibility. Community services need to develop in a way that allows them to meet such preferences as expansion of existing services alone may not necessarily translate into reduced acute hospital service use. Increasing the number of inpatient hospice beds may be one possible solution.

Limitations

There are limitations to this study. As with all qualitative research it is possible that our findings were influenced by the researcher's personal biases and/or experience. We attempted to address this by using a maximum variation sampling strategy and performing dual coding for a selection of interviews. Although member checking of the interview transcripts and/or study findings could have further enhanced the rigour of our results, this was unable to be performed due to the rapid deterioration of many of the participants.

The setting (London) of our study is likely to have influenced some of our findings. Compared to other more rural settings patients in London have greater access to acute hospital care. Community healthcare services are also known to vary by region. Some of our study findings may therefore not be applicable to people living in different environments, especially those in more rural settings.

We also only interviewed patients who had decided to seek ED care meaning that the decision-making process of those who used alternative services was not explored. Future research exploring whether the issues identified remain relevant to patients who choose community services would provide further insight and understanding of this topic.

Finally, it is important to acknowledge that for many people acute hospital care does not represent an adverse event. In many situations the ED is the most appropriate setting for urgent care needs to be investigated and managed, and the importance of providing individualised patient-centered care, including ED care if needed, should not be overlooked.

CONCLUSIONS

Drawing on Padgett and Brodsky's modified version of the 'Behavioral Model of Health Services Use', this study provides new evidence for *why* and *how* patients with advanced cancer decide to seek ED care. Issues influencing the decision-making process included: (1) disease-related anxiety; (2) prior patterns of health-seeking behaviour; (3) feelings of safety and familiarity with the hospital setting; and, (4) difficulties accessing community healthcare services—especially urgently and/or out-of-hours. These insights provide healthcare professionals and policymakers with a greater understanding of how systems of care may be developed to help reduce ED visits made by people with advanced cancer. In particular, our findings suggest that the number of ED visits could be reduced with greater end-of-life symptom support and education, earlier collaboration between oncology and palliative care and with increased access to community healthcare services.

Acknowledgements The authors acknowledge the additional support received from Marie Curie Cancer Care and the Collaboration for Leadership in Applied Health Research and Care (CLAHRC) South London, National Institute for Health Research (NIHR). The CLAHRC is a partnership between King's Health Partners, St. George's, University London, and St George's Healthcare NHS Trust.

Contributors IJH and BAD participated in conception and design. LH was involved in data collection and writing of the manuscript with critical revisions by all other authors. LH, CE-S, JK and MM participated in data analysis and interpretation. All authors approved the final version of the manuscript.

Funding BuildCARE is supported by Cicely Saunders International (CSI) and The Atlantic Philanthropies, led by King's College London, Cicely Saunders Institute, Department of Palliative Care, Policy and Rehabilitation, UK. CI: Higginson. Grant leads: Higginson, McCrone, Normand, Lawlor, Meier, Morrison. Project Co-ordinator/PI: Daveson. Study arm PIs: Pantilat, Selman, Normand, Ryan, McQuillan, Morrison, Daveson. We thank all collaborators and advisors including service-users. BuildCARE members: Emma Bennett, Francesca Cooper, Barbara Daveson, Susanne de Wolf-Linder, Mendwas Dzingina, Clare Ellis-Smith, Catherine J Evans, Taja Ferguson, Lesley A Henson, Irene J Higginson, Bridget Johnston, Paramjote Kaler, Pauline Kane, Peter Lawlor, Paul McCrone, Regina McQuillan, Diane Meier, Sean Morrison, Fliss E Murtagh, Charles Normand, Caty Pannell, Steve Pantilat, Ana Reison, Karen Ryan, Lucy Selman, Melinda Smith, Katy Tobin, Rowena Vohora, Wei Gao.

Competing interests None declared.

Ethics approval UK National Research Ethics Service Committee South Central—Berkshire (REC reference 14/SC/1207).

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement No additional data are available.

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Chapter 7 - Integration and Discussion

7.1 Overview

The overall aim of this study was to understand variation in cancer patients' end-of-life ED use in order to support the development of future initiatives aimed at reducing high attendance and improving equity of access to end-of-life healthcare services. A review of the scientific literature revealed a limited understanding of cancer patients' end-of-life ED use. Most of the existing research focused on quantifying attendance and/or investigating factors associated with an increased risk of multiple ED visits towards the end-of-life (65, 66). Whilst these studies identified various socio-demographic, clinical and environmental risk factors, important gaps in the literature were highlighted. Data from the UK, with its unique publicly funded model of healthcare delivery, was absent. There were also limited and/or conflicting results for several factors, such as patients' level of co-morbidity, cancer diagnosis and rurality of usual place of residence. Qualitative research exploring why advanced cancer patients decide to attend the ED was limited (67, 68). Moreover, an integrated summary of the factors associated with end-of-life ED visits (quantitative research) and the decision-making processes of advanced cancer patients to seek ED care (qualitative research) was lacking.

This mixed methods study was designed to address these gaps: quantitative methods were used to investigate factors associated with end-of-life ED visits by people with cancer in England, UK (Publications 2 and 3); a qualitative interview study was conducted to explore advanced cancer patients' and their caregivers' decisions to seek ED care (Publication 4). This chapter combines the quantitative and qualitative findings, and discusses the relevance of the integrated findings to clinical practice, policy and service development. A conceptual model developed from the results is then presented, depicting the main factors and concepts – and the presumed

relationships between them – contributing to the phenomenon of cancer patients' end-of-life ED use.

7.2 Integration

7.2.1 Demographic Factors

Demographic differences in end-of-life ED attendance by people with cancer are well reported in the literature (87-89). This is exemplified by the findings of the systematic review conducted, which found high-quality evidence (meta-analysis) for an increased risk in end-of-life ED visits for men, younger patients and people of Black ethnicity. The population-based retrospective cohort study explored these factors for the first time in a UK population, and the findings were consistent with those of the systematic review. Men were found to have an increased odds of multiple ED visits during the last month of life (adjusted odds ratio (AOR) 1.26, 95% confidence interval (CI) 1.19-1.34, reference group female) (

Figure 7.1), as were people of Asian or Black ethnicity (AOR 1.49, 95% CI 1.27-1.74 and AOR 1.21, 95% CI 1.01-1.46 respectively, reference group White ethnicity). Also consistent with the systematic review findings was an increased odds of multiple ED visits in the last month of life for younger patients.

The qualitative component of this study further explored these demographic factors. One important finding that emerged was the relationship between patients' age and disease-related anxiety. Patients' anxiety about their cancer was one of four key concepts that emerged from the qualitative interviews as influencing patients' and their caregivers' decisions to seek ED care; and patient's age appeared to mediate this anxiety. Compared to younger patients, older patients described feeling less anxious about their cancer diagnosis and were also less likely to perceive and/or interpret their physical symptoms as being severe or cancer related.

(A)

(B)

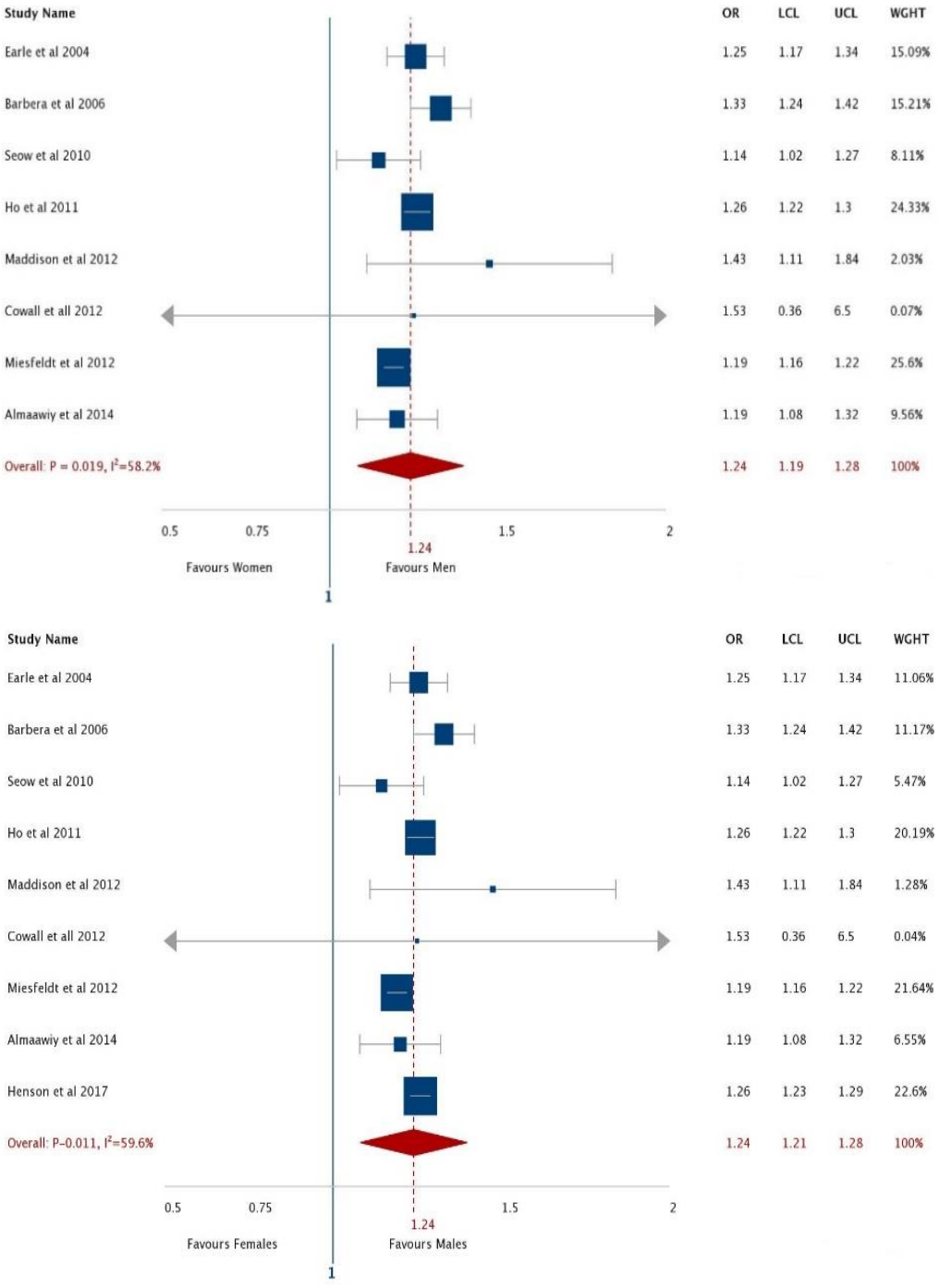

Figure 7.1: Forest plot illustrating the effect of sex on cancer patients' ED attendance in the last month of life

Meta-analysis of odds ratios using random-effects model. (A) Results from systematic review meta-analysis; (B) Systematic review meta-analysis with results from present study added.

This is not to say that older persons were less anxious overall, rather, that the issues causing anxiety varied across age groups. Whilst younger patients described more anxiety regarding physical symptoms and their cancer diagnosis, older patients reported feeling anxious about practical day-to-day tasks, such as getting washed and dressed each morning. These differences offer one explanation for the quantitative finding that younger patients have an increased risk of attending the ED multiple times in the last month of life compared to older patients.

The qualitative interview study did not provide further insight into the associations found between end-of-life ED visits and other demographic factors, i.e. male sex and Asian or Black ethnicity. However, as per the findings for age, one hypothesis is that these differences are due to varying health beliefs across different ethnic groups and between men and women. This hypothesis is supported by studies that have shown differences in symptom perception across socio-demographic groups, and those that have found certain health beliefs and behaviours to be distributed unequally across society (90, 91). For example, studies have shown that the uptake of screening and preventative healthcare appointments is greater for women, younger persons and those of White ethnicity (54). An alternative hypothesis is that the quantitative variation seen is secondary to different preferences for end-of-life care (92-97). In a survey of 2,536 patients aged >65 years, Garrett et al. found that after adjustment for factors such as marital status, 53% of women had a desire for less treatment if they were to have a terminal illness compared to 42% of men (93). With regards to ethnicity, Smith et al. found that African-American patients with a terminal illness were more likely than White patients to want cardiopulmonary resuscitation, dialysis and other life prolonging treatments (98). Furthermore, in a multi-site prospective cohort study examining ethnic disparities in advance care planning and preferences for end-of-life care, Smith et al. found that African-American patients were less likely to acknowledge having a terminal illness and to want to discuss their prognosis compared to White patients (99). This study challenges the hypothesis that the demographic variation in

end-of-life ED use is secondary to different preferences for care. Firstly, preferences did not emerge during the qualitative interviews as a concept influencing patients' and their caregivers' decisions to seek ED care. Whilst it could be argued that the action of attending the ED, as opposed to seeking care elsewhere, was a reflection of patients' preferences, the qualitative interview study did not support this interpretation. Rather, patients described having no other option than to attend the ED (quote 1), and some stated a preference not to be in an acute hospital setting (quote 2).

Quote 1: Qualitative interview conducted with participant ED07, an 80-year-old man with Acute Myeloid Leukaemia who presented to the ED with a temperature

LH [interviewer]: Did you want to come to hospital?

ED07: Hadn't got any choice 'cause outpatients said to me if it [temperature] ever goes above 38, you've gotta come in. (LH: Okay) You've gotta come in.

Quote 2: Qualitative interview conducted with participant ED01, a 66-year-old man with Hepatocellular Carcinoma who presented to the ED with abdominal pain

ED01: Well I think, like I said, on reflection…mmm [pause] acute medical admissions ward isn't the best place (LH [interviewer]: Okay) to be when you're sitting with this kind of stuff. I know everyone's got their own difficulties, err and maybe other people in here have terminal illnesses as well. Erm [pause] but I've just felt on occasions you know that, the kind of business of the place and err. [pause] I've seen some obviously really quite unwell people. (LH: Mmm) I'd prefer to be somewhere a bit quieter and alone I think.

Furthermore, this hypothesis was not supported by the qualitative findings regarding patients' religious/spiritual beliefs. Previous research has identified an association between religious beliefs and a desire for more aggressive end-of-life care (100, 101). For example, in a study of

patients with advanced cancer who had failed first line chemotherapy, Balboni et al. found an association between religiousness and a desire for all measures to extend life (odds ratio (OR) 1.96, 95% CI 1.08-3.57) (101). However, the qualitative interviews conducted as part of this study found that instead of precipitating a decision to attend the ED, religiousness was a mediator of disease-related anxiety, and for many patients helped them cope with their illness (quote 3).

Quote 3: Qualitative interview conducted with participant ED18, a 46-year-old woman with metastatic Breast Cancer who presented to the ED with back pain

> *ED18: You know I'm I'm a Christian and I'm a believer, I'm I'm I'm a born-again believer so…my faith is very strong in in what I believe, and, that really takes care of a lot of the the burden if I should say, (LH [interviewer]: Okay) you know. When when I get to a state where I get like a bit of a wimp, I pray.*

One explanation for this difference may be the timing of the interviews (post ED attendance) and the type of situations being explored (urgent/acute issues) (102, 103). Most of the evidence regarding patients' preferences for end-of-life care comes from survey and questionnaire studies which typically ask participants about their preferences for care given various hypothetical future scenarios. In reality, preferences for care can change over time and with experience of illness (104-108). In a qualitative interview study with people who had experience of pancreatic cancer (eight patients; eight bereaved relatives), Chapple et al. found that preferences for care were influenced by participants' prior healthcare experiences (109). This study supports those findings and provides further evidence that patients' prior health-seeking behaviour is important in shaping their future use of healthcare services. The population-based retrospective cohort study found a dose-response pattern between patients' prior ED use and risk of multiple ED visits in the last month of life (Figure 7.3). Findings from the qualitative interview study were complementary; at times of crisis participants' described defaulting to

services they had previously used and were familiar with. Furthermore, the qualitative interview study highlighted the complexity of patients' decision-making and the wide variation in cancer patients' experiences at the end-of-life. Most of the patients interviewed were well informed about their diagnosis and many talked candidly about the future and their expectations of death. Yet despite having considerable knowledge and insight, most of the events that precipitated patients' and their caregivers' decisions to attend the ED had not been anticipated or planned for.

Summary of Integrated Demographic Findings

The integrated findings of this study support previously conducted research showing an association between demographic factors (male sex; younger age; Black ethnicity) and an increased odds of multiple ED visits in the last month of life. Rather than different preferences for end-of-life care, the findings of this study suggest that the variation in end-of-life ED use is due to different health beliefs, such as symptom interpretation, across demographic groups.

7.2.2 Clinical Characteristics

Level of Co-Morbidity

Previous studies have explored the relationship between cancer patients' level of co-morbidity and end-of-life ED use (50, 87, 89), and overall, the findings have been mixed. This study found a dose-response relationship between cancer patients' level of co-morbidity and odds of multiple ED visits in the last month of life. Compared to patients with a co-morbidity score of zero, patients with a score of 1 or ≥2 were more likely to visit the ED multiple times (AOR 1.31, 95% CI 1.23-1.39 and AOR 1.53, 95% CI 1.43-1.63 respectively). Consistent with these findings are those of Ho et al. who found a positive trend between cancer patients' level of co-morbidity and odds of multiple ED visits in the last 30 days of life (50). Similarly, Barbera et al. found that patients with a Charlson co-morbidity score of ≥2 were more likely visit the ED in their last two

weeks of life compared to those with a score of 0 or 1 (AOR 1.099, 95% CI 1.016-1.189) (89). In contrast to these findings were those reported by Seow et al., Maddison et al. and Almaawiy et al., all of whom found no significant association between patients' level of co-morbidity and end-of-life ED use (87, 110, 111). Further interpretation of these findings is challenging due to the variation in how co-morbidity was categorised across studies. The qualitative interview study did not identify co-morbidity as a concept influencing cancer patients' ED use and therefore was unable to support or explain the quantitative findings.

One hypothesis that could explain the mixed results is that the relationship between co-morbidity and ED use is confounded by patients' mobility and/or risk of falls. Overall, it appears that patients with either low or very high co-morbidity scores are less likely to visit the ED towards the end-of-life compared to those with medium or high scores. Patients with low co-morbidity scores are likely to have a lower risk of falls compared to those with medium or high scores. This positive trend between co-morbidity score and risk of falls would continue up until a certain threshold point when the number of co-morbidities (corresponding to a very high co-morbidity score) would correlate with patients becoming chair or bedbound, and consequently significantly reducing or eliminating their risk of falls. The quantitative study found that musculoskeletal disorders/injuries (including fractures) was the third most common reason for patients' attending the ED in the last month of life. Issues with data quality meant that this relationship could not be explored further, however it is possible that part of this relationship can be explained by injuries secondary to falls.

Type of Cancer and Symptoms Experienced

The retrospective cohort study found that patients with lung or head and neck cancer have an increased risk of multiple ED visits in the last month of life (AOR 1.74, 95% CI 1.56-1.95 and 1.67, 1.40-2.00 respectively, reference group colorectal cancer), and that respiratory symptoms are

the most common ED presenting complaint. These findings are in keeping with existing studies that have shown an increased risk of multiple ED visits in the last month of life for patients with lung cancer (50, 51, 65, 89, 111, 112), and studies that have found breathlessness to be the most common presenting symptom of cancer patients who attend the ED or are admitted to hospital during their last days of life (113, 114). Less evidence exists for the relationship between end-of-life ED visits and other cancer types, although individual studies have reported an increased likelihood of ED visits for patients with haematological malignancies (50), hepatocellular carcinoma and oesophageal cancer (65).

People with lung cancer may be more likely to visit the ED towards the end-of-life due to the speed and pattern with which lung cancer spreads throughout the body. In the UK, just 32% of patients diagnosed with lung cancer are alive at one year, compared to 94% and 96% of prostate and breast cancer patients respectively (11). When there is a short amount of time between diagnosis and death, advance care planning is often more challenging, as patients can still be receiving treatment and coming to terms with their diagnosis when their health begins to deteriorate. This hypothesis is not, however, supported by patterns of ED use seen with other cancers that have a similarly poor prognosis. For example, people diagnosed with pancreatic cancer have a 21% chance of survival at one year, but have not been found to have an increased risk of multiple end-of-life ED visits. The qualitative interview study expanded on these findings, revealing that certain symptoms, in particular breathlessness, were more likely to be interpreted as severe and/or requiring urgent review, compared to other symptoms. Although patients with many different types of cancer can experience breathlessness, it is most commonly experienced by those with lung cancer (115). The relationship between patients' symptom experiences and their ED use is an important area for future research. Unfortunately, issues with data quality limited further quantitative analysis of patients' symptoms in this study.

Summary of Integrated Clinical Findings

The integrated findings of this study support a dose-response relationship between cancer patients' level of co-morbidity and end-of-life ED attendance up until a certain threshold point when a very high co-morbidity score reduces risk. This relationship may be confounded by patients' mobility and/or risk of falls. This study also supports previously conducted research showing an association between an end-of-life ED visits and a diagnosis of lung cancer, which may be related to an increased prevalence of breathlessness in this patient group.

7.2.3 Environmental Factors

This study investigated the relationship between cancer patients' end-of-life ED use and the following environmental factors: socio-economic status (SES); community healthcare services; contact with palliative care. The relationship between patients' prior ED attendance and ED visits in the last month of life was also determined.

Socio-Economic Status

SES is known to correlate with the aggressiveness of end-of-life cancer care including the risk of multiple ED visits in the last month of life (116-119). In line with these findings, the retrospective cohort study found people with a higher SES had a lower odds of multiple ED visits in the last month of life (AOR 0.84, 95% CI 0.77-0.92, reference group lowest SES). The consistency of these findings is of particular interest given that these data come from countries with different healthcare systems and policy. In the UK, the NHS provides healthcare that is free for all at the point of delivery. Yet despite this, significant differences in the aggressiveness of end-of-life cancer care based on SES remain. Furthermore, evidence that improvements to the UK's overall delivery of end-of-life care have not reduced inequality across socio-economic groups is concerning (120, 121). The qualitative interview study did not provide further insight into this

relationship, however, as for demographic factors, a potential mechanism of action could be differences in patients' health beliefs across social class.

Community Healthcare Services

The relationship between community healthcare services and ED attendance is important especially when considering the structure of future services and policy. Results from the secondary analysis of pooled data from two mortality follow-back surveys found that patients were more likely to experience an indicator of aggressive end-of-life care if they had: <5 GP home visits during their last three months of life (AOR 2.70, 95% CI 1.22–5.88, reference group ≥5 GP visits); and, no contact with district nursing (AOR 2.08, 95% CI 1.20–3.57, reference group district nursing contact). The dataset supplied by NHS Digital did not include any community healthcare service variables; therefore, the specific relationship between patients' ED attendance in the last month of life and their use of community healthcare services could not be determined. The qualitative interview study did however provide further insight into the relationship between patients' use of community healthcare services and end-of-life ED attendance. Access to community healthcare services emerged as a key theme that influenced patients' and their caregivers' decisions to seek ED care. Participants described difficulties accessing community healthcare services, especially urgently and/or out-of-hours. Participants also described the hospital setting and staff as more familiar to them than community services and staff. Previous studies have identified continuity of care as important to patients' quality of life (14, 122, 123) and their use of healthcare services (111, 124). Whilst the availability of community healthcare services is important, so also is healthcare provider continuity and trust; patients described their decision-making as being influenced by both. The most striking evidence for this came from the divergent findings of one qualitative interview. This interview was conducted jointly with the patient and his caregiver (son). Both described a positive and trusting

relationship with their GP to the extent that they would always seek their GP's advice before attending the ED (quote 4).

Quote 4: Qualitative interview conducted with participant ED17, who was the son of participant ED16, an 86-year-old man with Lung Cancer who had recently attended the ED:

LH [interviewer]: So tell me more about what happened when the GP came. So you phoned up, and it sounded like it was quite straightforward.

ED17: Yeah erm we phoned-up. [phone rings] Sorry I'll just switch this off. [pause]

ED17: Erm, yeah we phoned reception, said is there any chance of a home visit? Said he was too weak for us to get down to the surgery and yep not a problem, he would come at the end of the surgery. He did, turned up…had a quick look over. Told him what the symptoms were, what our concerns were, and we said said to him right said this normally coincides with needing a transfusion, and he went maybe, we said like his stool's black and he explained that that could be down to the iron which it turned out what it was (LH: Okay) and err you know certainly agreed that he definitely needed re-hydrating, and he called for the ambulance. (LH: Okay) He didn't leave us to do it he got onto the surgery and said request an ambulance within the next two hours. (LH: Okay).

Contact with Palliative Care

The systematic review conducted found high-quality evidence (meta-analysis) of a reduced odds of ED visits in the last month of life for cancer patients receiving palliative care (pooled OR 0.43, 95% CI 0.36-0.51, reference group patients not receiving palliative care) (Figure 7.2). Consistent with the systematic review, the secondary analysis of pooled data from two mortality follow-back surveys found a reduced risk of aggressive end-of-life care for patients who had contact with community palliative care services (AOR 0.27, 95% CI 0.15-0.49, reference group no contact with community palliative care services).

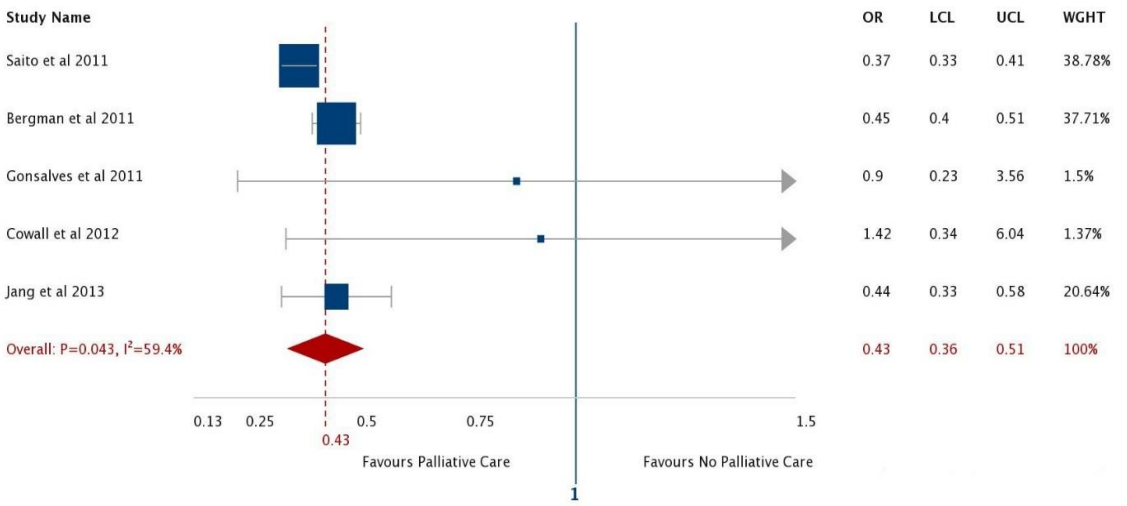

Figure 7.2: Forest plot illustrating the effect of palliative care services on cancer patients' ED attendance in the last month of life

Meta-analysis of odds ratios using a random-effects model (125-129).

The qualitative interview study highlighted a number of different mechanisms by which contact with palliative care services might reduce patients' end-of-life ED use. Firstly, patients reported how, at times of crisis, they defaulted to services they had prior experience of and to healthcare professionals they trusted. Palliative care helped bridge a transition between patients receiving mostly hospital-based care (via the oncology team), to receiving mostly community-based care. Rather than there being a distinct handover from one service/specialty to the next, palliative care helped support a transition in patients' care and encouraged relationships that developed more naturally over time.

Secondly, participants described how palliative care services provided them with education and support for their symptoms. Even though patients' perceptions of their symptoms tended to remain, education, for example about pain and the use of analgesic medication, meant that it was possible for some patients to manage their symptoms out-of-hours and seek help from non-urgent healthcare services, such as their regular GP, the following day.

The qualitative findings also identified important times when community palliative care services would be unlikely to prevent an ED visit. In particular, the issue of safety and being able to abdicate responsibility emerged. Participants described feeling anxious at home and wanting to be somewhere 'safe'. Several participants reported feeling reassured when practical tasks were performed, such as their blood pressure being taken. In these circumstances, despite no acute intervention being required, the hospital environment was important to patients, suggesting that even with greater availability of community healthcare services, these visits might still have occurred.

Patients' Prior Emergency Department Attendance

Research has shown that patients' prior use and experiences of healthcare services influences their future use (130-132). For example, Greenlick et al. found the most powerful discriminator of whether a man would respond to an invitation for cardiovascular screening was whether he had received any medical care in the preceding two years (130). Prior to this study, the relationship between cancer patients' previous ED use and ED attendance towards the end-of-life had not been explored. The retrospective cohort study found a dose-response pattern between patients' prior number of ED visits and their attendance in the last month of life. Compared to patients with no ED visits in the 11 months prior to the last month of life, the odds of multiple ED visits during the last 30 days increased with each additional visit, p for trend <0.001 (Figure 7.3). These novel findings were supported by those of the qualitative interview study. Patients described defaulting to services they had prior experience of when faced with an acute/urgent situation. They also described challenges in accessing community healthcare services and feeling reassured by the hospital environment which allowed them to abdicate responsibility for their ongoing care.

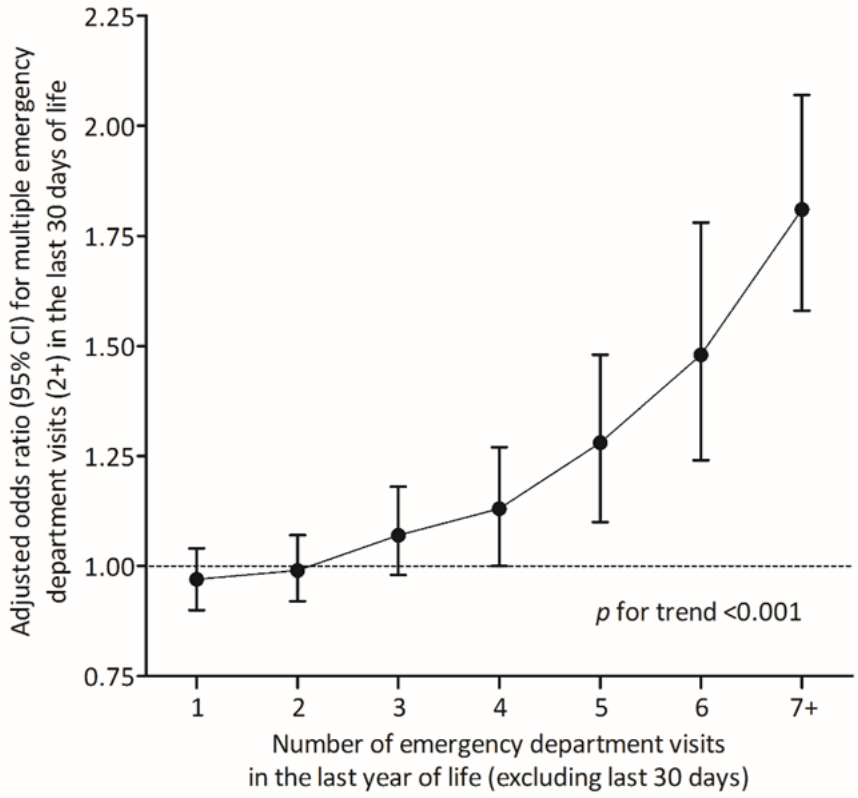

Figure 7.3: Relationship between cancer patients' prior ED attendance and odds of multiple ED visits in the last 30 days of life
(Publication 3)

Summary of Integrated Environmental Findings

The integrated findings support an association between environmental factors (low SES; fewer community healthcare services; no palliative care) and an increased odds of multiple ED visits in the last month of life. A dose-response pattern between patients' prior number of ED visits and their attendance in the last month of life was also found. The relationship between SES and end-of-life ED visits is hypothesised to be due to different health beliefs and behaviours across social class. For community and palliative care services, and prior ED visits, issues of access, safety, and trust and familiarity with certain healthcare services, were all identified as important.

7.3 Conceptual Model

The integrated findings of this study have been used to develop a conceptual model. In this model the main factors and concepts – and the presumed relationships between them – contributing to the phenomenon of cancer patients' end-of-life ED use are presented.

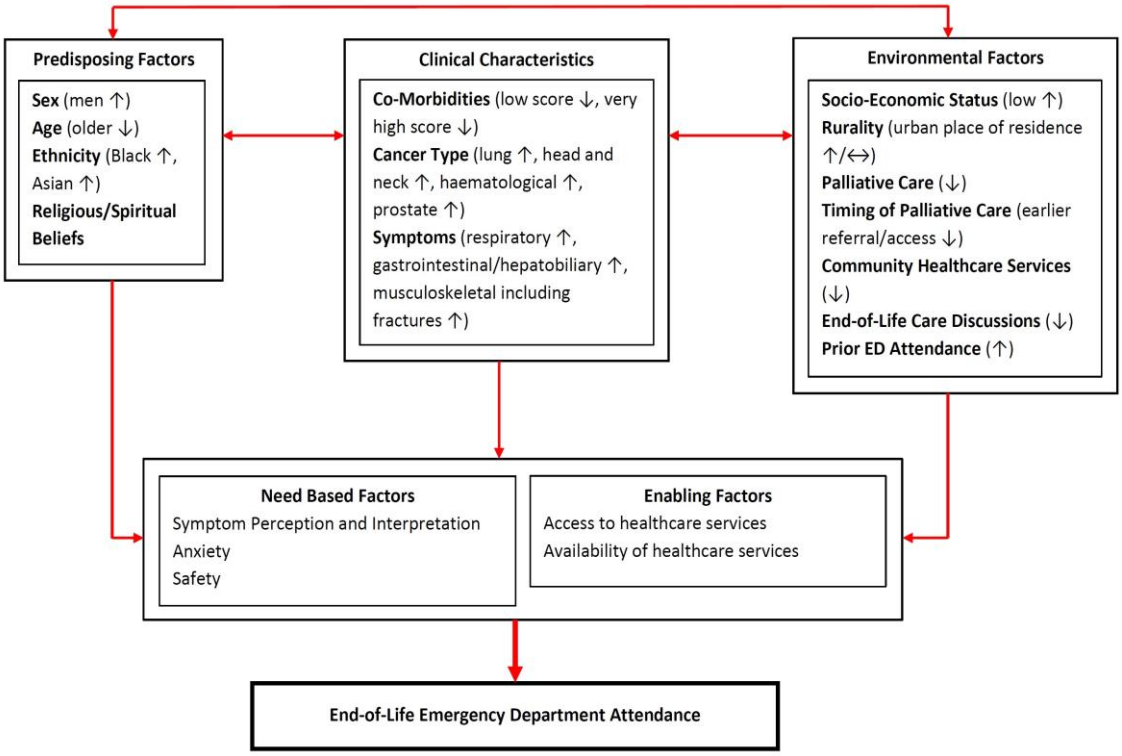

Figure 7.4: Conceptual model

7.4 Strengths and Limitations

The strengths and limitations of this mixed methods study are detailed below, including the decision to employ mixed methods, the use of existing models of health-seeking behaviour and the choice of ED attendance as an indicator of the quality of end-of-life cancer care. The strengths and limitations specific to each study component are presented in their corresponding publications. These discussions are not repeated below apart from those regarding the use of routine data for which further reflection is warranted.

7.4.1 Use of Mixed Methods

One of the key strengths of this study was the decision to employ mixed methods. The underlying logic for mixing quantitative and qualitative data is that individually, neither method would be sufficient for capturing the detail and complexity of the study subject (69). By utilising the strengths of both quantitative and qualitative approaches, mixed methods research can be particularly beneficial when investigating complex behavioural and/or clinical scenarios (73, 74, 133). The phenomenon of cancer patients' end-of-life ED use is complex, dynamic and multi-faceted. A mixed methods study was therefore ideal as it allowed a more in-depth and complete analysis to be conducted. Furthermore, prior to this study, an integrated summary of cancer patients' end-of-life ED use, based on quantitative and qualitative data, was lacking.

In summary, by employing mixed methods, this study was able to:

1) Determine factors associated with cancer patients' end-of-life ED use for the first time within a UK population (quantitative component).
2) Add to the limited research exploring advanced cancer patient's health-seeking behaviour (qualitative component).

3) Develop the first conceptual model of the factors and concepts – and the presumed relationships between them – contributing to the phenomenon of cancer patients' end-of-life ED use (quantitative and qualitative components).

Although the decision to use mixed methods was considered a key overall strength, it also presented challenges. Knowledge of both quantitative and qualitative methodologies was required, as well as additional time to plan and conduct each component and then integrate the findings. With a background in clinical medicine I have experience of prioritising activities and managing multiple work strands, and whilst I found this experience valuable, my skills were not directly transferable to the research setting. In clinical medicine 'tasks' or 'jobs' are mostly completed in minutes to hours, for example admitting a patient to hospital. There is also guidance on prioritising activities and an expectation to handover outstanding tasks at the end of each shift. In the research setting, tasks would typically take me weeks or months to complete. Keeping on track of the study's overall progress was often difficult, and on occasions I was unsure when a task had been completed and lacked confidence to move to the next stage of the study or acknowledge that a change in direction was required. During these times I was guided by my supervisors. I learned the importance of flexibility and pragmatism when conducting clinical research, experiencing first-hand that despite best intentions, research studies don't always go as planned. This was particularly evident when delays accessing data from NHS Digital required me to explore alternative quantitative datasets. Initially I found this difficult and struggled to see past the limitations. However, as the process continued I came to appreciate that all datasets have strengths and limitations, and completing a study with an acknowledgement of these limitations is much better than striving, and then failing, to deliver the perfect study.

7.4.2 Models of Health-Seeking Behaviour

A further strength of this study was its use of extant models of health-seeking behaviour, including Andersen and Newman's Behavioural Model of Health Services Use, Young's Choice-Making Model, and Padgett and Brodsky's modified version of the Behaviour Model of Health Services Use (55, 57, 59). These models highlighted important concepts worthy of investigation, guided the quantitative and qualitative integration process, and also provided a framework for the conceptual model developed.

The use of existing models also had limitations. None of the models identified were developed, or had been applied, to patients with advanced cancer and/or at the end-of-life. This meant that concepts specific to the health-seeking behaviour of this population would be missing from the models. Furthermore, some of the underlying health and behavioural theories that the models were built on do not necessarily translate to those at the end-of-life. The 'sick role', a term coined by Talcott Parsons in 1951, is one of the earliest and most recognised health and illness theories (134). One of the underlying assumptions of the sick role is that 'health is a good thing, illness a bad thing and thereby the doctor and patient must want and strive towards regaining health' (134). However, for those approaching the end-of-life, these assumptions don't necessarily hold true; instead the focus of care typically shifts away from life-extending treatments and towards maximising the quality of life remaining. These limitations were acknowledged from the outset and highlighted the importance of using the information gained from the models as a guide, rather than attempting to fit the findings of this study to one of the existing models/theories. To aid this process, models specific to palliative and end-of-life care, for example Gomes and Higginson's Model of Variations of Place of Death, were also considered (135).

7.4.3 Use of Routinely Collected Health Data

The quantitative component of this study used routinely collected mortality data from the ONS linked to routinely collected ED data from HES (72). This linkage created a bespoke dataset with a number of strengths. The use of routine data negated the need for primary data collection, therefore saving both time and money. The dataset also contained valuable population-level data for a vulnerable group of patients – those in the final weeks of life – who are often excluded from clinical trials due to recruitment challenges and/or high levels of attrition (136).

Limitations of the dataset mostly related to issues of data quality. Many of the dataset's clinical variables (supplied by HES) were unsuitable for analysis due to high levels of missing and/or invalid data. The systematic literature review conducted as background to this study, identified clinical characteristics as an important concept requiring further investigation. It was therefore particularly disappointing that data quality issues meant it was not possible to explore the relationship between cancer patients' end-of-life ED use and a number of clinical variables, such as symptoms. I have since reflected on whether this limitation could have been anticipated and/or attenuated. All of the HES ED variables are described in a data dictionary which was reviewed at the time of the NHS Digital application (137). Figure 7.5 provides an example of the type of information contained in the dictionary for each variable.

The data dictionary (137) did not provide any information about data quality apart from the following statement at the beginning of the document:

> *There are known weaknesses in the data, but rather than withhold this already useful dataset we have released it as 'experimental' and are seeking feedback from data suppliers and users to help us bring about rapid improvements and developments needed to support key NHS business and policy areas. (p.3).*

HES field name	Arrival mode
Field	aearrivalmode
Class	Attendances
Length and format	1n
Availability	2007-08 onwards
Description	
The mode by which a patient arrived at an A&E department.	
Value	
1 = Brought in by ambulance (including helicopter / Air Ambulance) 2 = Other 9 = Not known	
Data cleaning	Rule 84

Figure 7.5: Example of information provided about Hospital Episode Statistics variables

Whilst I expected that the dataset would contain variables with limited and/or unusable data, I did not consider which variables would most likely be affected and how this might impact the overall study. Compared to socio-demographic factors, empirical data describing the relationship between patients' clinical characteristics and their end-of-life ED use is limited. This is likely to reflect issues of data quality more broadly and highlights some of the current challenges of using routinely collected healthcare data for research. Addressing the validity of clinically coded variables is an important next step towards maximising the value of such resources.

7.4.4 Emergency Department Use as a Performance Indicator

Fundamental to this study was the decision to explore ED use as a marker of the quality of end-of-life cancer care. This decision was based on several factors. Firstly, the proportion of patients with multiple ED visits in the last month of life is a validated indicator of overly aggressive end-of-life cancer care (26), and consistent high-quality evidence exists for a link between overly aggressive end-of-life cancer care and poor patient and caregiver outcomes (61, 63, 138).

Secondly, routinely collected population data is available for all NHS ED visits in England, but prior to this study, had not been used to examine the quality of end-of-life cancer care. Thirdly, ED use continues to receive intense social and political attention. Across developed countries, EDs are facing considerable pressure to evolve and become more efficient, whilst also experiencing ever increasing demand and expectations of care. Empirical data that can help understand patients' ED use is essential to support service development and healthcare policy.

Using ED attendance as a marker of end-of-life care quality has limitations. It is important to acknowledge that the proportion of patients with multiple ED visits in the last month of life is an indicator of the quality of end-of-life cancer care at a population level, not an individual level. In many situations the ED is the most appropriate setting for urgent care needs to be investigated and/or managed, and in such circumstances ED attendance should be encouraged. By promoting end-of-life ED use as a performance indicator there is a risk that all end-of-life ED visits will be interpreted as representing poor quality care. This has been a criticism of previously used performance measures, for example the proportion of people dying in their own home (139).

Evaluating the quality of end-of-life care is challenging and examining isolated performance measures, such as ED use, may not accurately represent the overall picture. For example, Teno et al. found a significant increase in the proportion of home deaths for Medicare beneficiaries in the USA between 2000, 2005 and 2009. In isolation this trend suggested that end-of-life care was becoming less aggressive over time. However, further analysis found that during the same time period there were significant increases in the number of end-of-life healthcare transitions and admissions to intensive care (test of trend $p<0.001$) (140). Whilst the proportion of cancer patients with multiple ED visits in the last month of life is a recognised indicator of end-of-life care quality, it is only one indicator, and as such, it should be interpreted and explored alongside other markers of end-of-life care quality, such as the proportion of patients receiving

chemotherapy in the last 14 days of life. Unfortunately, exploration of these additional measures was beyond the scope of this thesis, however future research exploring these relationships is planned.

Lastly, for future populations, the proportion of patients with multiple ED visits in the last month of life may no longer be a valid indicator of overly aggressive end-of-life cancer care. With the effects of population growth and ageing, the future average cancer patient will be older and more likely to have one or more co-morbidities. Oncology treatment and care is also developing rapidly, with treatments becoming increasingly available to those with advanced disease and in the later stages of illness. It can be hypothesised that older patients with more co-morbidities who continue to receive active oncological treatment will have greater acute care needs and an increased demand for hospital care towards the end-of-life. In this context, re-exploring the validity of ED use as an indicator of overly aggressive end-of-life care would be important.

7.5 Implications for Clinical Practice, Healthcare Policy and Future Research

7.5.1 Implications for Clinical Practice

Relevant to healthcare professionals and clinical practice, this study has highlighted the complexity of individuals' decision-making and the importance of patients' symptom perception and interpretation. Clinical medicine requires healthcare professionals to regularly review patients' symptoms or take what is known as a 'symptom history'. During this process, a healthcare professional will ask a patient a series of questions pertinent to their symptom(s) in order to generate a list of possible diagnoses. Further investigations and/or treatment can then be organised accordingly. During the qualitative interview study patients were asked to describe and explain the symptom(s) that led to them seeking ED care. Whilst my training as a palliative care physician has afforded me considerable opportunities to develop my history taking and communication skills, conducting qualitative interviews made me listen to patients differently.

By completely emerging myself in a patient's narrative, without trying to seek a diagnosis or develop a management plan, I more fully appreciated the meaning that certain symptoms had to patients' and their caregivers. This in turn helped me understand patients' thought processes and their resulting behaviours. Concepts such as safety would not have been identified without this qualitative approach and has led to me reflecting on the meaning of this to clinical practice. This study has highlighted the value of using a different approach to history taking. The importance of listening and being able to adapt communication styles for different clinical situations and/or patient groups is evident. Future research exploring how different history taking approaches influence patients' end-of-life care and their use of healthcare services would be valuable (141-144).

7.5.2 Implications for Healthcare Policy and Future Research

For managers and policy-makers, knowledge of high-risk patient characteristics can help with allocating resources and planning future services. This is especially important given the ageing population and anticipated rise in cases of cancer. This research determined that in England, between 01/04/2011 and 31/03/2012, 30.7% (n=38,049) of cancer decedents attended the ED once during their last month of life and 5.1% (n=6,325) attended multiple times. With population growth and ageing these figures can be anticipated to increase to n=46,454 and n=7,717 respectively by 2030, highlighting the extent and urgency with which healthcare services need to evolve.

During the earlier stages of this study I proposed using the research findings to develop an early warning system or screening tool. Early warning systems are a major component of disaster risk reduction strategy, having been developed from the understanding that 'although disasters often appear to happen suddenly with little or no prior warning, in fact, most disasters incubate over long gestation periods during which warning events accumulate' (p. 1071) (145). Their use

extends from predicting and warning of natural disasters to the forecasting of impending financial crises (145). An effective early warning system involves the regular analysis of routine information that may be predictive of a future threat or hazard, with the aim of providing sufficient warning for preventative action to be taken. When developed and implemented well, early warning systems have been shown to save lives. For example, The Nationwide Operational Assessment of Hazards (NOAH) Project is an early warning system that was initiated by the Philippines government to warn of intense weather conditions, and in 2012, it enabled more than 167,000 people to be evacuated to safety prior to Typhoon Bopha (146). Within the healthcare setting, early warning systems have been successfully integrated into clinical practice, so much so that in 2007 NICE recommended the use of physiological track and trigger systems for all adult hospital in-patients (147).

The use of early warning systems across other healthcare disciplines led to me considering their role in palliative and end-of-life care. The quantitative findings of this study could be used to develop an early warning system capable of identifying cancer patients with an increased risk of multiple ED visits towards the end-of-life. This could be used to improve patient outcomes through various mechanisms, such as triggering an earlier referral to palliative care services (148-151). Future research testing and evaluating such an intervention is planned.

This research has also highlighted the importance of understanding the context and complexity of patients' healthcare utilisation. The pace of change in healthcare and pressure on services to evolve immediately present many challenges, including for researchers. Many randomised controlled trials and quasi experimental studies have failed to make an impact beyond the study setting and it may be that pressure to assess the effectiveness of interventions has led to large-scale quantitative analyses being conducted before an adequate understanding of the research problem has been compiled. Mixed methods research may reduce some of these issues.

Incorporating a qualitative component to studies that would have traditionally been solely quantitative, could help researchers understand and interpret their quantitative research, as well as support the implementation of the research findings to other settings.

7.6 Conclusions

Socio-demographic (younger age; male sex; Asian or Black ethnicity; low socio-economic status), clinical (high co-morbidity score; diagnosis of lung or head and neck cancer) and environmental (fewer community healthcare services; lack of palliative care; high previous ED use) factors are associated with an increased risk of multiple ED visits towards the end-of-life by people with cancer. Issues influencing advanced cancer patients' and their caregivers' decisions to seek ED care are complementary and propose underlying mechanisms of action for the quantitative associations found. Difficulties accessing community healthcare services and feelings of safety and familiarity with the hospital setting appear to support the quantitative environmental factors, whilst disease-related anxiety may explain some of the variation found in ED use across different socio-demographic groups. The findings provide evidence for the development of future interventions to address these aspects. These may include: 1. Early warning systems or screening tools based on the quantitative factors, leading to earlier engagement with relevant services such as palliative care; and, 2. Support for healthcare professionals in exploring patients' health beliefs, in particular their interpretation of symptoms.

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Appendix A - NHS Digital Data Application Form, Correspondence and Approval Documents

hscic Health & Social Care Information Centre

HSCIC Data Linkage & Extract Services

Applicant details

Office use only

Date application received

Reference number

Introduction

Please fill out the form with as much information as possible. Completed forms should be sent to enquiries@hscic.gov.uk

If you have any problems using this form please contact the applications manager on **0845 300 6016.**

Any feedback on the usability of this form would be appreciated.

****

Fill in the sections of this form as per the table below:

Section	Who should fill this section in?	Tick to indicate which sections you have completed
Section 1	All applicants	
Section 2	Applicants requesting services to support research	☐
Section 3	Applicants requiring any of the following services: • Patient status • Patient tracking	☐
Section 4	Applicants requiring any of the following services: • Data tabulation or extract (HES[1], PROMS[2], ONS[3], HES-ONS[4], HES-PROMS[5], PBR[6]) • Linkage to a dataset listed above	☒
Section 5	Applicants intending to send in data to the HSCIC to be linked	☐
Section 6	Applicants requesting, or sending in, sensitive or patient identifiable fields	☐

Any applications for HES, PROMS, ONS or PBR data must include the relevant field list forms: http://www.hscic.gov.uk/article/2074/Data-extract-application-forms

****

Section 1

All applicants are to complete this section.

You must provide the address(es) where any data that we send to you will be stored.

Contact details		
Name:	Dr Lesley Henson	
Organisation name:	Kings College London	
Telephone:	020 7848 5689 / 020 7848 5516	
Email address:	lesley.henson@kcl.ac.uk	
Address: Please include addresses for all organisations where data will be stored (for collaborative projects)	Registered company/organisation address:	Address where data will be stored (if different): Continue on a separate sheet if necessary
	Department of Palliative Care, Policy and Rehabilitation, Cicely Saunders Institute, Bessemer Road, London	N/A
Postcode:	SE5 9PJ	

Data is delivered using an electronic file transfer system. Please provide the name and email address of the person who will be responsible for **downloading** the **data from** the HSCIC.

Person receiving data from HSCIC		
Name:	Gao Wei	**Email:** wei.gao@kcl.ac.uk

If you are sending in data to be linked, please provide the name and email address of the person responsible for **sending it in** to the HSCIC (if different to above)

Person sending data to HSCIC		
Name:		**Email:**

Other users – Every person using the record level data must be listed in this section. (Please continue on an additional sheet if necessary)		
Name	Organisation (if different to applicant)	Job Title
Dr Gao Wei		Medical Statistician (Lecturer)
Dr Barbara Daveson		Research Fellow
Prof Irene Higginson		Director CSI, Head of Department, Professor of

		Palliative Care and Policy. Honorary Consultant King's College Hospital NHS Trust

Licensee Confirmation

(Please complete the relevant section below depending whether your intended usage of the data is for Academic or Non- Academic use);

Licensee Confirmation – For Academic Use Only

(Please complete if you have selected the above 'Academic Institution' or 'Student/Individual' categories; Please leave this section blank and skip to the section below if your request is not for Academic Use)

On requesting this data we will be sending you a contractual Data Re-use Agreement (DRA) If you wish for the Licensee of this agreement to be named as a University or Academic Institute, please confirm that you have the required authority to enter a contractual agreement on the behalf of this Institute. If '**Yes**', please specify the name of the University/Academic Institute that should be named as the Licensee.	**Please Confirm;** Yes ☒ Named Licensee Kings College London No ☐ *(See below)*
If you selected '**No**', then your application will be processed under '**Private Individual Academic Research**' use; If this is the case then, you, the individual applicant, should be named as the Licensee for this request. Please confirm this by entering the Individual applicant's name.	**Please specify the Individual applicant to be named as the Licensee;**

Licensee Confirmation – For Non Academic Use

(Please complete if your request is not for Academic Use)

On requesting this data we will be sending you a contractual Data Re-use Agreement (DRA). Please can you confirm that your requesting organisation (as specified in your above contact details) is a legal corporate entity and is able to enter into this contractual agreement as the named Licensee.	**Please Confirm;** Yes ☒ No ☐ *(See below)*
If you have selected '**No**', please specify the organisation that should be named as the Licensee for this data request; e.g. the applicants Hosting Organisation.	**Confirmation of the named Licensee;**

Data Re-use Statement
A full description (no more than 400 words) of the purpose for which access to data is required needs to be detailed below. I.e. • Why are you requesting data? • How will you use the data? • What will the outputs of your analysis be? ***NOTE: Please provide full details in this section, further details will be requested if insufficient information is provided and this will delay your application.***

I am a PhD student in the Department of Palliative Care, Policy and Rehabilitation at King's College London. My PhD is focusing on emergency department attendance in patients with advanced cancer towards the end of life. I'm planning to use linked ONS HES data to describe the current patterns in the UK of cancer patient's use of emergency services towards the end of life. This study will form part of a larger overall study with the aim of trying to reduce emergency department attendance in cancer patients through developing interventions to help support their care at home.

The data will be used to describe trends in use of emergency department attendance and identify factors associated with emergency department use based on cancer type and proximity to death.
Study Aim:
- To explore the factors associated with, and impact of, UK ED attendance in patients with advanced cancer.

Objectives:
- To determine what symptoms cause adult patients with advanced cancer to present to the emergency department
- To determine the clinical diagnoses made for adult patients with advanced cancer who present to the emergency department
- To describe the outcomes of patients with advanced cancer who present to the emergency department, including length of hospital stay in those patients admitted, place of discharge, place of death, and procedures and investigations performed.
- To describe how the above factors are affected by cancer type
- To describe how the above factors are affected by stage of disease

I plan to publish the research results to a relevant peer reviewed journal. The research will also form part of a PhD thesis investigating emergency department use in advanced cancer patients.

Data retention, storage and destruction Data may be retained beyond the specified time periods below subject to a renewal of your agreement	
Up to 12 months *You must select for ONS, PROMS, sensitive or identifiable data*	☒
Up to 36 months Only possible for non-sensitive data	☐

Section 2

N/A

All applicants requesting services to support research must complete this section.

Does your research satisfy all of the following conditions? This question is used to help us direct your request to the most appropriate team		
	Yes	**No**
Use patient level information	☐	☐
Have the intention to answer a specific research question	☐	☐
Is intended to benefit public health &/or advance medical science	☐	☐
Is undertaken using a structured methodology, set out in a protocol approved by both an appropriate ethics and scientific approval committee	☐	☐
Will be put in the public domain by peer reviewed or web based publication or provision of results to a regulator	☐	☐

Have the relevant ethics committee(s) been consulted?
☐ Yes - please supply the ethics committee response letter(s)
☐ No

Title of the study (this will be the name by which the study will be referred to in any publication)

Study aims:

State what the aims of the study are in less than 200 words Note: the potential value and public interest of the research are important factors taken into account when considering requests.

State the background of the study in less than 200 words

Give a detailed outline of the study methods, being specific about what you require of the HSCIC

Section 3

N/A

All applicants requiring patient status or tracking must complete this section.

Will the information we provide be used to make direct contact with (please tick all that apply)

- ☐ Hospital consultants
- ☐ GPs of study subjects
- ☐ Relatives of study subjects
- ☐ no other party to be contacted
- ☐ Other staff in hospitals where study subjects are treated
- ☐ Study subjects found to be alive
- ☐ Other party

How will contact be made?

- ☐ Letter
- ☐ Phone
- ☐ Other (please specify)

How did you identify your study population?

- ☐ Employee records
- ☐ Hospital records
- ☐ Clinical trials
- ☐ GP records
- ☐ Survey questionnaires
- ☐ PCT
- ☐ Other (please specify)

Please specify how many members you have in your study			
England & Wales:		**Scotland:**	

How many members were alive on 01/01/1991?
Our computerised records commenced 1991

England & Wales:		**Scotland:**	

Details of the commissioning/sponsoring organisation
Please provide a letter from the commissioning organisation confirming their involvement

Organisation	
Address	
Postcode	

N/A.

Name & address of funding organisation if different to organisation named above	
Organisation	
Address	
Postcode	

What is the grant period?			
From:		To:	

Section 4

All applicants requiring tabulations or extracts of data (HES, PROMS, ONS, PBR) must complete this section.

You must include the relevant field selection forms with your application.

Previous HES use	
Is this request an update of an earlier extract or a new application?	Update ☐ New ☒
If you have requested the HES patient identifier (Extract_Hesid) and require this to be encrypted using the same key as a previous extract, please enter the extract specification reference number (ET#### / TDLS###)	

Territory of Use	
Please indicate using the options below, the use to which you intend to put the requested data (please select all the relevant options):	
Please confirm the "Territory" that you wish to utilise the data in the end use of products or services supplied by you. **Please note that we may require further information for requests to send the data outside of England.*	☒ England ☐ UK* ☐ Europe* ☐ Worldwide*

Intended Market of Re-Use	
Please indicate using the options below, the market(s) that the requested data will be used / re-used by or supplied for:	
HSCIC product or service being requested and used by a **NHS and Social Care organisation or other** public body in pursuance of its own "public task" objective.	☐
HSCIC product or service to be used by any organisation for the purpose of improving the quality of healthcare management and service delivery **in England** and **NOT involving a commercial transaction.**	☒
HSCIC product or service to be used by any organisation for the purpose of improving the quality of healthcare management and service delivery **in England** and **involving a commercial transaction.**	☐
All other intended uses (Including Private sector use)	☐

Section 5

N/A

All applicants intending to send in data for linkage should complete this section.

What information can you provide to us for matching?	
☐ **NHS Number**	☐ **Date of birth**
☐ Surname	☐ Place of birth
☐ Forenames	☐ Last known address
☐ Initials	☐ **Postcode**
☐ Any other name used	☐ Date of death
☐ **Sex**	☐ Other (please specify)

Please note that if you are requesting a linkage to HES, HES-PROMS or HES-ONS data, without NHS number tracing required, only the bold items should be provided in addition to a dummy record ID assigned by you.

Section 6

N/A

All applicants requesting, or sending in, sensitive or identifiable data should complete this section.

Has written permission been obtained from:	
☐ Consultants	☐ Individuals
☐ GPs	☐ Other (please specify)

Give a brief description of the consent sought and provide copies of the consent forms used/to be used. If consent has not been sought please give a brief description why not:

Date recruitment starts/started?	
DD/MM/YYYY	

Date recruitment completed/expected to be completed?	
DD/MM/YYYY	

If consent has not been obtained do you have support under section 251 of the NHS Act 2006?
☐ Yes - please supply a copy of the approval letter ECC[7] ref number:
☐ No

Please note that any requests for sensitive data items may need to be referred to the Data Access Advisory Group (DAAG). We will contact you about this if necessary.

Notes

1. Hospital Episode Statistics
2. Patient Reported Outcome Measures
3. Office of National Statistics mortality data
4. HES-ONS linked data
5. HES-PROMS linked data
6. Payment by Results
7. Ethics & Confidentiality Committee

Appendix A:

Information Security Assurance for Identifiable, Sensitive and or ONS Data (that we send to you – you do not need to fill this section in if you are sending us in identifiers for linkage and not requesting any sensitive/identifiable/ONS fields back).

Applicant Security Responsibilities

The licensee understands and accepts that it becomes the data controller in common for personal (identifiable) data received from the HSCIC. As such the licensee is responsible for processing the data in accordance with the Data Protection Act 1998 and maintaining good information governance standards and practices. The licensee also understands and accepts that it becomes the data custodian for sensitive personal data. As such the licensee is responsible for processing the data in accordance with any specific legal or regulatory standards applied to the data in question.

To provide assurance that good Information Governance practices are being maintained the licensee can demonstrate and will allow the HSCIC to audit that it: (please tick appropriate box)

meets or exceeds the Information Governance Toolkit standards required for their organisation type, where applicable. (please provide organisation code and score ☐

is Certified against international security standard ISO 27002 (please provide certification details) ☐

has other assurance in place (please provide details) ☒

King's College London is working towards obtaining ISO 27002 certification. At present the assurances in place are those as outlined by the project PI and supported by the legal compliance manager of KCL.

In cases where these assurance standards are not appropriate, the licensee will ensure it meets the following requirements, which the HSCIC reserves the right to audit.

As a data controller/data custodian, with respect to the data being provided by the HSCIC, the licensee undertakes to ensure that:

a) It processes personal or sensitive personal data only for medical purposes, and only for purposes described in the data sharing agreement with the HSCIC which it assures are also consistent with the purposes recorded in the licensee's data protection registration with the Information Commissioner's Office;

b) It processes the minimum data necessary (e.g. using age range rather than age if sufficient)

c) It deploys secure processes, procedures, practice and technology for storage and access, commensurate with the personal or sensitive personal data being processed

d) It ensures no individual other than those to be named on the Agreement will access the data, and that all computer terminals and other means of access are maintained securely in secure premises.

e) It ensures the rights of individuals are met, such as satisfying subject access requests received, ensuring data accuracy and correcting errors, and handling objections and complaints

f) It destroys the data once it is no longer required for the purposed for which it was collected;

g) It ensures all employees with access to the data provide a written undertaking that they understand and will act in accordance with their responsibilities under the Data Protection Act , will not share passwords, and will protect the confidentiality of the data they access

h) It reports immediately to the HSCIC any security incidents relating to use of the supplied data, and any instances of breach of any of the terms of this Agreement.

i) It complies with any specific legislation in relation to the data provided by the HSCIC e.g. Statistics and Registration Services Act 2007.

j) It signs a Data Re use Agreement prior to the release of any data by the HSCIC.[1]

Signed For and on behalf of:

Kings College London <Insert Organisation Name>

Signed[2]

Print Name: ANNE CAMERON

Post/Title: DATA PROTECTION OFFICER – LEGAL COMPLIANCE MANAGER

Date: 24 SEPTEMBER 2013.

<Insert Organisation Name>

<Insert Organisation Address>

[1] *Data Re Use Agreement; a document that will outline the specific details of the customer request and data release conditions*

[2] *Must be signed by the Caldicott Guardian or Senior Information Risk Owner*

HSCIC Data Extract Service

HES-ONS linked mortality data Application Form

Appendix D: ONS Microdata Release Procedure (MRP)
Customer Request Form

Introduction

Customers who require HES-ONS linked data for uses not approved under the NHS Act 2006, should complete this application form. See Section 4.5 and Figure 1.1 in the HES Extract Guide on HESonline [http://www.hesonline.nhs.uk] for more details.

Step 1:

It is necessary to obtain accreditation as an Approved Researcher in order to obtain approval for the ONS data through the Microdata Release Panel at the Office for National Statistics.

Please complete the Approved Researcher application form – How to become an Approved Researcher - available at the link below:

http://www.ons.gov.uk/ons/about-ons/who-we-are/services/unpublished-data/access-to-ons-data-service/index.html

Please note: **ALL** individuals wishing to access the ONS data **MUST** complete and submit a **signed** Approved Researcher application form.

Step 2:

Complete and sign:
Appendix D: ONS Microdata Release Procedure (MRP) Application Form

Step 3:

Complete and sign:
Data Access Agreement: Appendix D3

Step 4:

Submit the Approved Researcher and Appendix D application forms to the Health & Social Care Information Centre at: enquiries@ic.nhs.uk

PLEASE NOTE: ALL ONS application forms must be signed.

Step 5:

The Health & Social Care Information Centre will submit your application to the Office for National Statistics for approval. Once approval is granted, you will be advised by the Health & Social Care Information Centre.

Appendix D1: HES-ONS linked data

Data year(s): 2010-2012

Data on death registrations by calendar year since 1998[1] is available, by default only ONS records which match to the associated HES extract will be provided. Please give details below if you require the data to be filtered further by the year in which the death occurred or was registered.

[1] Deaths registered before Jan 2001 contain original underlying cause of death and cause of death mentions coded in ICD 9

Other details Data year details
All deaths from cancer (ICD-10, version for 2012, Chapter II, Neoplasms, (C00-C97)) for a 12 month period beginning 01/04/2011 to 31/03/2012. These ONS records linked to HES accident and emergency data for the years 01/04/2010 to 31/03/2012 **and** all inpatient HES hospital data for the same time period (01/04/2010 to 31/03/2012).

Requested fields ***please select*** ☒

For an explanation of the fields in this section, please refer to the field descriptions in the Mortality Data Dictionary [http://www.hesonline.nhs.uk/Ease/servlet/ContentServer?siteID=1937&categoryID=289].

ONS mortality data

All fields selected here require ONS approval.

☒**Checked fields are provided for all extracts**

☒ Extract HESID
☒ Date of death (dod)
☒ Date of registration (oor)
☒ Strategic Health Authority of usual residence of deceased (resstha)
☒ Primary Care Trust of usual residence of deceased (respct)
☒ Sex
☒ Communal establishment (place of death code)
☒ NHS indicator
☒ Original underlying cause of death (cause_of_death)
☒ Non-neonatal cause of death mentions (cause_of_death_non_neonatal)
☐ Neonatal cause of death mentions (cause_of_death_neonatal)
☐ Neonatal cause of death row positions[2] (cause_of_death_row_pos)

☒ Match rank[3] – Linkage derived field relating to match quality

☒ Death record used[4] – indicates source of the linked death record, HES or ONS

☒ Subsequent activity[5] – indicates whether the patient has had any HES activity after the date of death (Subsequent_activity)

[2] [3] [4] [5] For further information relating to match ranks, death record used and subsequent activity fields please refer to the Mortality Data Dictionary [http://www.hesonline.nhs.uk/Ease/servlet/ContentServer?siteID=1937&categoryID=289].

Other details – if you require any further filters to be applied to your data please provide details below:

Previous extract number

Please provide your previous HES extract number if you have one N/A

(This will allow you to receive extract HESIDs which are compatible with your previous extract.)

Notes:

Time taken for ONS approvals: 6 to 8 weeks

Provisional nature of the linked mortality data
The data from the ONS-HES linkage is provisional, as it changes over time.

The Office for National Statistics provides mortality data on a monthly basis which is provisional in nature. ONS provisional data has not been subject to full quality assurance and may not contain all deaths which were registered or which occurred during the period. Deaths which occurred in a given year may be registered in a subsequent year. The database remains open to accept these registrations so figures are subject to change. ONS also supplies a final annual refresh of mortality data for the year which is based on calendar year of death registration.

HES data for the latest financial year is provisional and may be incomplete or contain errors for which no adjustments have yet been made. Counts produced from provisional data are likely to be lower than those generated for the same period in the final dataset. This shortfall will be most pronounced in the final month of the latest period, i.e. November from the (month 9) April to November extract.

Due to the complexity of the linkage process, efforts are being made continually to improve the linkage algorithm. Figures may also change due to occasional upgrades to the linkage algorithm. Any changes made to the algorithm will be detailed in the Mortality page on HESonline. Changes to the linkage algorithm or delays in receiving the ONS mortality data can cause delays in the linkage period illustrated above.

Appendix D2: MRP – Customer Request Form

Office for National Statistics

OFFICE FOR NATIONAL STATISTICS

MICRODATA RELEASE PROCEDURE (MRP) – CUSTOMER REQUEST FORM

The MRP is ONS' centralised process for authorising access to unpublished ONS data. Requests for access are submitted for approval to the Microdata Release Panel, which acts with the authority of the National Statistician. Requests will be approved, that meet the MRP criteria, and are consistent with the aims and principles of the Code of Practice and the Protocol on Data Access and Confidentiality.

Where the organisation requiring the research contracts another organisation to conduct that research, this form is to be completed by the contracting organisation and the details of the contracted organisation, i.e. the contracted researcher/s, are to be entered into section 2.

To enable your request to be submitted for consideration, please complete the following form providing sufficient detail to enable the Panel to make a fully informed decision.

1. Details of the Applicant.

Please complete the following:

1.1 Name and contact details of applicant

Name:	Dr Lesley Henson
Position:	PhD Clinical Training Fellow
Email Address:	lesley.henson@kcl.ac.uk
Telephone Number:	020 7848 5689

1.2 Name and full address of the organisation

Name:	Kings College London
Address:	Department of Palliative Care, Policy and Rehabilitation, Cicely Saunders Institute, Bessemer Road, Denmark Hill, London, SE5 9PJ
Email Address:	palliativecare@kcl.ac.uk
Telephone Number:	020 7848 5516

1.3 Main statistical contact (if different from 1.1)

Name:	Dr Gao Wei
Position:	Medical Statistician (Lecturer)
Email Address:	wei.gao@kcl.ac.uk
Telephone Number:	020 7848 5570

1.4 The individual who will ultimately be responsible for the data and has the authority to enter their organisation into a binding agreement (if different to 1.3).

Name:	Anne Cameron
Position:	Data Protection Officer and Legal Compliance Manager, King's College London
Email Address:	anne.cameron@kcl.ac.uk
Telephone Number:	020 7848 4344

1.5 The individual who will take delivery of the data (if different to 1.3)

Name:	As in section 1.3
Position:	
Email Address:	
Telephone Number:	

1.6 Name/s of all those who will access the data

Dr Lesley Henson, Dr Gao Wei, Prof Irene Higginson

2. Is a contractor to be employed? (NO) Please delete as required.

If YES, please complete the following:

2.1 Name and address of the contracted organisation N/A

Name:	
Address:	
Email Address:	
Telephone Number:	

2.2 Main statistical contact (contractor)

Name:	
Position:	
Email Address:	
Telephone Number:	

2.3 The individual who will ultimately be responsible for the data (contractor)

2.4 The individual who will take delivery of the data (where different to 2.2)

N/A

2.5 The name/s of all those who will be accessing the data

3. Location.

3.1 Please state the site where the data will be accessed

Department of Palliative Care, Policy and Rehabilitation, Cicely Saunders Institute, Bessemer Road, Denmark Hill, London. SE5 9PJ

3.2 If the location address is different from the address provided in 1.2 or 2.1 please give reasons

NA

4. Arrangements for access to the data

Please complete the following:

4.1 The Data Protection Registration / Notification no: of the contacting organisation/institution (if registered under the Data Protection Act)

Z7915194

4.1.1 The Data Protection Registration / Notification no: of the contractor (if registered under the Data Protection Act)

NA

4.2 Where hard copies of the data (eg CD/floppy disk) will be stored (e.g. locked filing cabinet)

On a password protected external hard drive that will be stored in a locked filing cabinet in a locked office within the department.

4.3 Where the data will be accessed (e.g. open plan office, secure locked room)

In an office within the department that is a secure locked room.

4.4 How data will be accessed e.g. using a stand-alone PC or a networked PC. If networked, please give details. (e.g. Local area network - LAN)

NB *(i) A PC can only be classed as stand-alone if not connected to the Internet or Local Area Network*

(ii) Please confirm that the PC will not be linked to the internet

(iii) Laptop computers/portable devices should not be used for confidential data

King's LAN networked PC

4.5 Controls in place to protect the confidentiality of the data (eg. firewalls, password protection on log-in)

The network is firewall protected. The PC has password protection on login.

4.6 Any other measures in place to protect the confidentiality of the data.

The data will be stored and accessed from a password protected encrypted iron-key, no one can access any file on an iron-key unless they authenticate with a correct password. After a customised number of incorrect password entries, the iron-key will self destruct.

4.7 Where you are requesting access to other than fully anonymised, non-disclosive data, please give details of your organisational security standards, and whether the IT systems in place meet BS ISO/IEC 27001 requirements or equivalent.

NA

5. Data requested. Please give full details including variables and level of data

6. The purpose for requiring the data.

6.1 A brief summary **(up to 100 words)**

The research proposed is part of a PhD in palliative care investigating emergency department attendance in patients with advanced cancer towards the end of life. I'm planning to use linked ONS HES data to describe the current patterns in the UK of cancer patients' use of emergency services towards the end of life. This study will form part of a larger overall study aiming to reduce emergency department attendance in cancer patients through developing interventions to help support their care at home.

6.2 A detailed description and explanation of your reason for requesting access to the data

Specific objectives of the project include:

- To describe and investigate the factors associated with emergency department attendance in patients with advanced cancer towards the end of life.

To construct risk models to help guide practice

7. Time period

7.1 The dates between which the data are required.

From: 01/04/2010	To: 31/03/2012

8. Products/Outputs

8.1 Details of the products/outputs that will be produced from your use of the data (e.g. analysis, reports, tables, books).

Analysis, reports, scientific publications, conference publications.

8.2 If any outputs, such as tables are to be produced, please state:

(i) The criteria to be used to decide whether it is disclosive or not (e.g. threshold rule)

All counts under 10 or any percentages/ rates will be suppressed to avoid disclosure. By differencing we will suppress additional cells where necessary.

(ii) Disclosure control treatments to be applied to outputs (eg primary/secondary suppression, conventional rounding).

We will apply the other measures (e.g. rounding, suppression of constant parameters) to safeguard disclosure of any information from outputs.

Please return the form to: enquiries@ic.nhs.uk

hscic Health & Social Care Information Centre

Data Linkage and Extract Service

Data Form for NHS Registration Data, Mortality Data and/or Cancer Registration Data

1. Introduction

This data form must be submitted with an application form, available from www.hscic.gov.uk/dlesapplications, when requesting any of the following:

- NHS Registration Data – i.e. data on patients' registration status within the NHS taken from the Personal Demographics Service (PDS)
- Cancer Registration Data – i.e. data on registered cancers within England and Wales
- Mortality Data – i.e. data on the fact, date and/or cause of death for NHS patients

For the release of mortality data, additional approval from the Office for National Statistics (ONS) is required. In order to receive mortality data, you must be eligible using one of three legal gateways and you may need to complete and submit additional forms (embedded within Section 3 of this form).

2. Description of the Products

The HSCIC holds a copy of the Personal Demographics Service (PDS), the national electronic database of NHS patient demographic details such as name, address, date of birth and NHS Number. The HSCIC links this data set to national cancer registration data. This matches registered cancers including information on the site, type and histology, with patient data.

The HSCIC is also able to access mortality data from the Office for National Statistics (ONS). The two data sets can be linked together or to other data sets.

Using these assets, the HSCIC offers the following products:

List Cleaning: Validating demographic data to improve linkage outcomes and/or ensure it is up to date prior to any contact.

Patient Status: A snapshot of current demographic status and mortality, including cause of death and/or cancer registration data where relevant.

Patient Tracking: Periodic long-term updates on the demographic status, cancer registrations and mortality of a cohort.

Linked HES-ONS Data: ONS data is routinely linked to Hospital Episode Statistics (HES) and made available as a standard extract. Data on death registrations by calendar year since 1998[1] are available. By default, only ONS records which match to the associated HES extract will be provided.

[1]Deaths registered before January 2001 contain original underlying cause of death and cause of death mentions coded in ICD 9. All death registered post 2001 will be coded in ICD 10.

Bespoke Linkages and Extracts: If the options above do not meet your exact requirements, please contact us to discuss a bespoke product tailored to meet your requirements.

3. Specific Conditions

3.1 Computerised Records

Computerised records of NHS registration data commenced in 1991 and ONS mortality data in 1993. Data from before this date is available but not in electronic format and, due to the manual processes required to provide pre-computerised data, additional charges will be applied. For further information please visit the applications, approvals and charges page.

3.2 Provisional Nature of Linked HES-ONS Data

The data from the HES-ONS linkage is made available as provisional data as neither data set has been subject to full quality assurance at the time of performing the linkage. The data quality is improved over time and annual refresh data is subsequently made available. Consequently there will be discrepancies if comparing provisional data against annual refresh data.

3.3 Legal Gateways to Access ONS Data

There are three legal gateways through which access to ONS mortality data can be granted:

3.3.1 Informed Patient Consent

In this case you will need to have obtained the explicit consent of the individuals to whom the data relates. You must supply copies of the consent materials used to gain individual explicit patient consent. This should include the consent forms and any literature such as information leaflets or posters.

3.3.2 Projects Covered by s42(4) of the SRSA 2007 amended by s287 of the Health and Social Care Act 2012

ONS data may be released if your project is considered to be covered by s42(4) of the Statistics and Registration Service Act 2007 amended by s287 of the Health and Social Care Act 2012 because:

(a) the information consists of statistics and is disclosed for the purpose of assisting the person in the performance of functions exercisable by it in relation to the health service, or

(b) the information is disclosed for the purpose of assisting the person to produce or to analyse statistics for the purpose of assisting the person, or any other person mentioned in subsection (4A), in the performance of functions exercisable by it in relation to the health service.

The persons named in subsection (4A) are:

a) the Secretary of State,

b) the Welsh Ministers,

c) the National Health Service Commissioning Board,

d) a clinical commissioning group,

e) a local authority,

f) a Local Health Board,

g) an NHS trust established under section 18 of the National Health Service (Wales) Act 2006,

h) the National Institute for Health and Care Excellence,

i) the Health and Social Care Information Centre,

j) a Special Health Authority,

k) the Care Quality Commission, and

l) such other persons as the appropriate authority may specify in a direction given for the purposes of this section. If any of the above criteria apply, you must supply a commissioning or funding letter from the relevant body.

3.3.3 Approved Researcher Accreditation

For applications to which neither of the first two legal gateways are applicable, accreditation as an Approved Researcher and approval from the ONS Microdata Release Panel is required. Approval for release of the data through this legal gateway is granted by ONS under the Statistics and Registration Service Act 2007 sections 23 and 39 (4) (i).

hscic Health & Social Care Information Centre

4. Legal Gateway for Accessing ONS Mortality Data

Only complete this section if ONS data is required.

4.1 Please indicate the legal gateway through which you wish to access ONS data:
☐ Informed Patient Consent – *proceed to Section 5*
☐ Projects considered to be covered by s42(4) of the Statistics and Registration Service Act 2007 amended by s287 of the Health and Social Care Act 2012 – *complete Sections 4.2, 4.3 and 4.4 then proceed to Section 5*
☒ Approved Research Accreditation – *complete Section 4.5*

4.2 Details of the commissioning/sponsoring organisation. Please provide a letter from the commissioning organisation confirming their involvement when submitting this application.	
Organisation	King's College London
Address	Department of Palliative Care, Policy and Rehabilitation, Cicely Saunders Institute, Bessemer Road, London
Postcode	SE5 9PJ

4.3 Name and address of funding organisation if different to organisation named above. Please provide evidence of funding if the funding organisation is different to the commissioning/sponsoring organisation named above.	
Organisation	
Address	N/A
Postcode	

4.4 Please specify when the funding period begins and ends			
From:		To:	

hscic Health & Social Care Information Centre

4.5 Approved Researcher Accreditation

The following forms must be completed (one per project):

- ONS 'Customer Request Form' (accessible here)
- ONS Data Access Agreement (see Appendix 1 below)

Each person requiring access to the ONS data must complete the following forms;

- ONS 'How to become an Approved Researcher' form (accessible here)
- ONS Short declaration of Use form(s) (see Appendix 2 below)

These forms will be submitted by the HSCIC to ONS for approval.

ONS will process the Approved Researcher applications first and once approved, will submit the request for data to ONS Microdata Release Panel (MRP). Requests will be approved subject to meeting the MRP criteria and being consistent with the aims and principles of the Code of Practice and the Protocol on Data Access and Confidentiality which ONS has in place.

5. Product(s) Requested

5.1 Please indicate the product(s) you require:

- ☐ List Cleaning
- ☐ Patient Status
- ☐ Patient Tracking – Select a reporting frequency:
  - ☐ Monthly
  - ☐ Quarterly
  - ☐ Biannual
  - ☐ Annual
  - ☐ Other frequency
- ☒ Standard Extract
- ☐ Bespoke Extract
- ☐ Other – please briefly describe [ ]

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5.2 Please indicate whether data to be provided by the HSCIC will be used to make direct contact with any of the following (please tick all that apply):

- ☐ Hospital consultants
- ☐ GPs of project subjects
- ☐ Relatives of cohort members
- ☒ No other party to be contacted
- ☐ Other staff in hospitals where cohort members are treated
- ☐ Cohort members found to be alive
- ☐ Other party (please specify) [ ]

5.3 If applicable, please indicate how contact will be made:

- ☐ Letter
- ☐ Telephone
- ☐ Email
- ☐ Other (please specify) [ ]

5.4 Please indicate how your cohort was or will be identified:

- ☐ Employee records
- ☐ Hospital records
- ☐ Clinical trials
- ☐ GP records
- ☐ Survey questionnaires
- ☐ Primary Care Trust (PCT) or Health Authority data
- ☐ Other (please specify) [ ]

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Only complete Sections 5.5, 5.6 and 5.7 if the products required include List Cleaning, Patient Status and/or Patient Tracking. If not, proceed to Section 5.8.

5.5 List Cleaning, Patient Status and Patient Tracking data requirements. If you require one of the above products, please indicate the specific data items you require from the HSCIC. NOTE: You should always request the minimum amount of data required and will need to provide a justification for identifiable data items in Section 2.1 of the application form, available at www.hscic.gov.uk/dlesapplications	
Latest Patient Information	
☐ NHS Number	☐ Surname
☐ Health Authority Cipher	☐ Forename
☐ GP Practice Code	☐ Middle/Other Name
☐ Details of de-registrations from and re-registrations within the NHS	☐ Address
☐ Cancer Registration Details	☐ Postcode
Death Details (ONS mortality data)	
☐ Fact of Death	☐ ICD 10th Revision Coded Cause(s) of Death
☐ Date of Death	☐ Cause(s) of Death (text)
De-identification/Pseudonymisation	
Do you require de-identified or pseudonymised outputs?	☐ Yes – please provide details [ ] ☐ No

5.6 Please specify the numbers of members in your cohort based in the following locations to the best of your knowledge:	
England & Wales	Scotland:

5.7 Please indicate how many members were alive on 01/01/1991 to the best of your knowledge:	
England & Wales	Scotland:

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Only complete Sections 5.8 to 5.11 if the products required involve a standard or bespoke extract from the linked HES-ONS data and/or linkage of that data to another data set.

5.8 Data Years required Please state the date range for which data is required (YYYY-MM-DD).	
From 01/04/2010	To 31/03/2012

5.9 Standard and/or Bespoke Extract data requirements. Please only complete this section if you require a linked HES-ONS extract. For an explanation of the fields in this section, please refer to the field descriptions in the mortality data dictionary, available at: www.hscic.gov.uk/hesdatadictionary. Please indicate the specific data items you require from the HSCIC. ☒ Checked fields are provided for all extracts. NOTE: You should always request the minimum amount of data required and will need to provide a justification for identifiable data items in Section 2.1 of the application form, available at: www.hscic.gov.uk/dlesapplications	
☒ Extract HESID	☒ NHS indicator
☒ Date of death (dod)	☒ Original underlying cause of death (cause_of_death)
☒ Date of registration (dor)	☐ Non-neonatal cause of death mentions (cause_of_death_non-neonatal)
☒ Strategic Health Authority of usual residence of deceased (resstha)	☐ Neonatal cause of death mentions (cause_of_death_neonatal)
☒ Primary Care Trust of usual residence of deceased (respct)	☒ Match rank[3] – Linkage derived field relating to match quality
☒ Sex	☒ Death record used[4] – indicates source of the linked death record, HES or ONS
☒ Communal establishment (place of death code)	☒ Subsequent activity[5] – indicates whether the patient has had any HES activity after the date of death (Subsequent_activity)

[2345] For further information relating to match ranks, death record used and subsequent activity fields, please refer to the mortality data dictionary, available at: www.hscic.gov.uk/hesdatadictionary

5.10 Additional filters
If you require any further filters to be applied to your data please provide details below:

5.11 Previous Extract Reference Number
If you have a previous HES extract reference number, please provide it below. This may be structured like: *ET1234*, *TDLS1234* or *DLS1234*. Providing this will allow you to receive extract HESIDs which are consistent with your previous extract(s).
N/A

Office for National Statistics

Appendix 1

DATA ACCESS AGREEMENT - ONS LINKED DATA

Agreement between the Office for National Statistics and

Organisation Name:	King's College London

1. Data required

Please state data years required:

01/04/2010 to 31/03/2012

2. Access Period
The period of access under this agreement is one year, but this agreement can be renewed on an annual basis.

3. Study title and purpose for which the data are provided

Please state: Study title.

Understanding Emergency Department Attendance by Advanced Cancer Patients towards the End of Life

Please state: Description of the purpose for requesting access to the linked HES-ONS mortality data.

The research proposed is part of a PhD in palliative care investigating emergency department attendance in patients with advanced cancer towards the end of life. I'm planning to use linked ONS HES data to describe the current patterns in the UK of cancer patient's use of emergency services towards the end of life. This study will form part of a larger overall study aiming to reduce emergency department attendance in cancer patients through developing interventions to help support their care at home.

Specific objectives of the project include:

- To describe and investigate the factors associated with emergency department attendance in patients with advanced cancer towards the end of life.
- To construct risk models to help guide practice

The HES-ONS Linkage data are supplied under the Statistics and Registration Service Act 2007 section 42(4) for the purpose of assisting the Secretary of State for Health, or the Welsh Ministers, in the performance of his, or their functions in relation to the health service. The information will only be used for the purpose(s) set out below – please tick as appropriate:

Needs Assessment	☐	Epidemiology	☒
Health impact assessment	☐	Small area statistics	☐
Monitoring of wider determinants of health	☒	Indicator development	☐
Monitoring of health improvement	☐	Target Setting	☐
Support for training and education in public health	☐		

If during the year additional uses of the data are identified, these should be notified to ONS for agreement.

4. Products and publications
4.1. No contact will be made with any individual identified in the information supplied without the prior approval of ONS.

4.2. The information will not be released to any other individual(s) or organisation(s) not directly connected with the work specified in section 3 without the prior approval of ONS, except in the form of non-disclosive statistical tables or conclusions.

4.3. All outputs resulting from access to these data must meet the guarantee contained in the Briefing Note: ONS policy on protecting confidentiality within birth and death statistics and the Code of Practice for Official Statistics.http://www.ons.gov.uk/ons/guide-method/best-practice/disclosure-control-policy-for-birth-and-death-statistics/index.html

4.4. To acknowledge in any publication, whether printed, electronic or broadcast, based wholly or in part on such materials, ONS as the provider of the materials. To declare in any such work that those who carried out the original collection and analysis of the data bear no responsibility for their further analysis or interpretation.

5. Minimum information needed
The level of data required is proportionate to the stated purpose(s). All the data provided are required to achieve the purpose(s) specified in section 3.

6. Matching or linking
Linkage of the information supplied to any other non-NHS information relating to identifiable individuals will only be attempted for the purpose(s) specified in section 3 and with the prior agreement of ONS.

7. Duplication
Any intended duplication of the data will only be for the purpose(s) specified in section 3. No other unspecified and unauthorised duplication of the microdata may take place.

8. Lawful use of the data
8.1. Data will be processed in accordance with the Data Protection Act (1998).

8.2. Access to these data will not breach any commitments made to respondents to protect the confidentiality of the data provided.

8.3 These data are released in accordance with the Statistics and Registration Service Act 2007 s42 (4) which states that the Board may, for the purpose of assisting the Secretary of State or the Welsh Ministers in the performance of his or their functions in relation to the health service, disclose to him or them any information referred to in section 42 subsection (2) (a - c):
a) any information entered in any register kept under the Births and Deaths Registration Act 1953 (c.20);
b) any other information received by the Registrar General in relation to any birth or death.

8.4. The information will only be used for the purpose(s) specified in section 3 and its use will meet the criteria and principles established in the Briefing Note: ONS policy on protecting confidentiality within birth and death statistics and the Code of Practice for Official Statistics.

8.5. The principles of the Freedom of Information Act apply and nothing provided in this agreement is confidential to the beneficiary or to ONS.

8.6. This data will be held by you on behalf of the United Kingdom Statistics Authority and are classified as 'personal information' according to the Statistics and Registration Service Act 2007.

8.7. The 2007 Act requires that you must not disclose the personal information that you hold on behalf of the Statistics Authority unless directly authorised by the National Statistician. Disclosure without this authority is a criminal offence

9. Arrangements when period of access expires

9.1. At the end of the access period data should be destroyed as follows and ONS further reserves the right to attend or audit the destruction of the data.

9.1.1. All departments must:

- destroy paper records containing protected personal data by incineration, pulping or shredding so that reconstruction is unlikely; and
- dispose of electronic media that have been used for protected personal data through secure destruction, overwriting, erasure or degaussing.

9.2. The beneficiary agrees to destroy all copies of the original data, including temporary copies, CDs, printed copies, personal copies, back-ups and all other electronic copies.

9.3. Where the beneficiary wishes to retain the original data, contact should be made with ONS prior to the end of the access period and a review of the access arrangements will be conducted. Subject to a satisfactory review, the data may be retained and a new access period agreed.

10. Security of the data

10.1. Registration/Notification number registered with the Data Protection Act:

Data Protection Number:	Z7915194

10.2. The responsible individual will ensure that their staff, including any contractors, know, understand and guarantee to maintain the confidentiality requirements of each of their statistical resources and will ensure that anyone involved with the processing of the statistical resource is aware of the penalties of wrongful disclosure.

10.3. The physical and technical security of the data will be maintained at all times. No disclosive information will be sent by fax or email (unless via GSI for a GSS customer) and, if posted, will be encrypted to approved standards (PGP or Private Crypto – not zipped) to protect the data and despatched by Royal Mail Special Delivery service or by courier.

10.4. Hard copies of the data will be stored securely in a locked filing cabinet. Access to the microdata will be restricted to those named on the Data Access Agreement who guarantee to protect and safeguard the confidentiality of the data at all times. Access to data will be via restricted-access password protection.

10.5. The beneficiary of the data will ensure that access to the data, any copies made of the data and the information contained in them is limited solely to the person(s) who have signed this Agreement. All other individual(s) who will have access to the data must sign the short declaration of use.

10.6. The confidentiality of the data will be preserved in outputs and publications, as detailed in section 4.

10.7. The means of access to the data (such as passwords or pass-phrases) are to be kept secure and only disclosed by the Beneficiary to those individuals who have signed short declarations of use.

10.8. Un-encrypted microdata will be stored on a secure network, with restricted access and no internet links, or on a stand-alone PC. The PC is to be password protected at boot-up.

10.9. Data will not be accessed at a private residence. Data will not be saved on laptops or other portable devices.

10.10 Laptops used to access data must be encrypted and secured to an HMG approved or recognised level, commensurate with the level of the protective marking of the data invo ved as will any network they are connected to.

10.11. Disclosive data must not be sent or taken out of the United Kingdom.

10.12. ONS reserves the right to conduct an on-site audit of the beneficiary's confidentiality and security procedures and practices for guaranteeing the security and confidentiality of the data covered by this agreement, or to require the report of such an audit.

10.12.1. For the purpose of conducting an audit, ONS reserves the right of entry to the premises where the data are stored and processed.

10.12.2. ONS may require the beneficiary to provide copies of any audits of these arrangements, conducted during the period of the agreement, including any audit implementation plans

11. Breach and Dispute Procedures.
11.1. The Statistics and Registration Service Act 2007 requires that personal information must not be disclosed by any 'person who has received the personal information directly or indirectly' from the ONS, unless directly authorised by the ONS. Disclosures of information that contravene section 39 of the Act will be an offence and may carry penalties, as specified in section 39(9).

11.2. The beneficiary agrees to report immediately to ONS instances of breach of any of the terms of this agreement

11.3. Any disputes arising between the providing and beneficiary organisations will be resolved initially between the principals to the agreement. Otherwise, outstanding issues will be referred to the National Statistician.

12. Approval
The signatories believe th s agreement is comp iant with the statements of principle n the Code of Practice for Official Statistics (The Code) and the specific requirements of the Protocol for Data Access and Confidentiality (PDAC). Where this agreement may appear to contradict the statements of principle in the Code or the specific requirements of the PDAC, the Code and the PDAC take precedence, unless explicitly stated.

12.1. Beneficiary Organisation
The responsible individual approves the terms of this Agreement and agrees to meet the requirements specified.

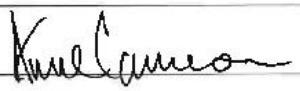
I ~~will take responsibility~~/have appointed:

Name (Print):	Dr Wei Gao

To take responsibility] for ensuring that the conditions of this agreement are fully complied with. We will ensure that ONS is informed of the name(s) of any person(s) who has access to the records supplied and that the named individuals have signed a declaration of use. The signature of the person agreeing to these conditions is appended. In the event that either of us ceases to have direct responsibility for these data within the organisation, a substitute ONS Data Access Agreement will be signed so as to have continued access to the data and/or any further data from ONS.

Office for National Statistics

Appendix 1

Name (print) :	Anne Cameron		
Position in Organisation:	Data Protection Officer - Legal Compliance Manager		
Email Address:	anne.cameron@kcl.ac.uk		
Telephone Number:	020 7848 4344		
Original Signature Required		**Date:**	26/09/13.

12.2. Declaration of Responsibility
I undertake to ensure that the data supplied by ONS and placed in my care by:

Name (print) :	Wei Gao

Is processed according to the above conditions.

Name (print) :	Wei Gao		
Position in Organisation:	Medical Statistician		
Email Address:	wei.gao@kcl.ac.uk		
Telephone Number:	020 7848 5570		
Original Signature Required	Gao Wei	**Date:**	25/9/13.

12.3. ONS Approval
The Responsible Data Custodian for the Office for National Statistics authorises the provision of access to the data to the beneficiary organisation under the terms specified in this Agreement

Status in Organisation:	D		
Name			
Original Signature Required		**Date:**	

Please return signed form to: Contact Centre, Health and Social Care Information Centre, 1 Trevelyan Square, Boar Lane, Leeds LS1 6AE

Or preferably by Email to: enquiries@hscic.gov.uk

Office for National Statistics

HES-ONS LINKAGE
SHORT DECLARATION OF USE

PLEASE NOTE: THIS FORM MUST BE COMPLETED BY ALL USERS ACCESSING THE RAW ONS DATA

I have read the conditions under which the HES-ONS Linkage extracts are supplied by ONS. (The conditions are part of the main Data Access Agreement.) I understand that my use of the data must be consistent with the conditions of supply. I will inform the person responsible of any actions that risk breaching their compliance with the conditions.

To Note: This data is now covered by the Statistics and Registration Service Act 2007 that requires that personal information must not be disclosed by any 'person who has received the personal information directly or indirectly' from the ONS, unless directly authorised by the ONS. Disclosures of information that contravene section 39 of the Act will be an offence and may carry penalties, as specified in section 39(9).

Organisation Name:	Kings College London
Position in Organisation:	International BuildCARE PhD Clinical Training Fellow
Organisation Address:	Department of Palliative Care, Policy and Rehabilitation, Bessemer Road, Denmark Hill, London
Postcode:	SE5 9PJ
Telephone number:	020 7848 5689
Email:	lesley.henson@kcl.ac.uk

Address where data will be accessed (if different from above):	As above
Postcode:	
Telephone number:	
Email:	

Name (print):	LESLEY HENSON		
Original Signature Required:		**Date:**	11.6.13

Office for National Statistics

HES-ONS LINKAGE
SHORT DECLARATION OF USE

PLEASE NOTE: THIS FORM MUST BE COMPLETED BY ALL USERS ACCESSING THE RAW ONS DATA

I have read the conditions under which the HES-ONS Linkage extracts are supplied by ONS. (The conditions are part of the main Data Access Agreement.) I understand that my use of the data must be consistent with the conditions of supply. I will inform the person responsible of any actions that risk breaching their compliance with the conditions.

To Note: This data is now covered by the Statistics and Registration Service Act 2007 that requires that personal information must not be disclosed by any 'person who has received the personal information directly or indirectly' from the ONS, unless directly authorised by the ONS. Disclosures of information that contravene section 39 of the Act will be an offence and may carry penalties, as specified in section 39(9).

Organisation Name:	Kings College London
Position in Organisation:	Director of Cicely Saunders Institute, Head of Dept, Prof of Palliative Care and Policy and Honorary Consultant King's College Hospital NHS Trust
Organisation Address:	Department of Palliative Care, Policy and Rehabilitation, Bessemer Road, Denmark Hill, London
Postcode:	SE5 9PJ
Telephone number:	020 7848 5516
Email:	irene.higginson@kcl.ac.uk

Address where data will be accessed (if different from above):	As above
Postcode:	
Telephone number:	
Email:	

Name (print):	IRENE HIGGINSON		
Original Signature Required:		**Date:**	12/6/13

Office for National Statistics

HES-ONS LINKAGE
SHORT DECLARATION OF USE

PLEASE NOTE: THIS FORM MUST BE COMPLETED BY ALL USERS ACCESSING THE RAW ONS DATA

I have read the conditions under which the HES-ONS Linkage extracts are supplied by ONS. (The conditions are part of the main Data Access Agreement.) I understand that my use of the data must be consistent with the conditions of supply. I will inform the person responsible of any actions that risk breaching their compliance with the conditions.

To Note: This data is now covered by the Statistics and Registration Service Act 2007 that requires that personal information must not be disclosed by any 'person who has received the personal information directly or indirectly' from the ONS, unless directly authorised by the ONS. Disclosures of information that contravene section 39 of the Act will be an offence and may carry penalties, as specified in section 39(9).

Organisation Name:	Kings College London
Position in Organisation:	Medical Statistician (Lecturer)
Organisation Address:	Department of Palliative Care, Policy and Rehabilitation. Bessemer Road. Denmark Hill, London
Postcode:	SE5 9PJ
Telephone number:	020 7848 5570
Email:	wei.gao@kcl.ac.uk

Address where data will be accessed (If different from above):	As above
Postcode:	
Telephone number:	
Email:	

Name (print):	Wei Gao		
Original Signature Required:	Gao Wei	**Date:**	14/06/13.

hscic Health & Social Care Information Centre

Health and Social Care Information Centre
1 Trevelyan Square
Boar Lane
Leeds
LS1 6AE

Tel: 0845 300 6016

enquiries@hscic.gov.uk
www.hscic.gov.uk

Dear HSCIC Customer

I am writing to explain the actions the HSCIC is taking in order to review our processes for handling the release of data. I apologise for any delays or confusion that you are experiencing in relation to this issue which is complex and has significant implications for our customers and partners.

Access to health data is currently being widely debated publicly and placed under some parliamentary scrutiny. We are committed to answering any concerns raised, as well as ensuring we are operating to the highest possible standards for the secure handling of confidential information.

We are undertaking a comprehensive review of all policies, processes and governance for the sharing of data, which involves ensuring there are appropriate approvals in place for any release of potentially identifiable data. We want all these processes and decisions to be accessible to the public and open to scrutiny. We are also reflecting on the implications of legislation currently going through parliament with the Care Bill, which aims to add further protections for individuals, including their right to object to the indirect use of their data.

We have adopted an interim set of arrangements for managing the release of data, aimed at demonstrating our commitment to building public trust while we carry out this review. I am committed to working collaboratively on this – the health and care system requires us to do so. We are therefore in the process of setting up more detailed discussions with our customers and partners.

In anticipation of these discussions, the following interim arrangements have been implemented with immediate effect:

- For customers who are awaiting renewal of their data sharing agreements, these will be considered for renewal on a short term basis for between three and six months, depending on what type of data is being requested and for what purpose the data is required.
- For customers who have data sharing agreements in place, data releases will continue until the renewed policies, process and governance are implemented for new requests and renewals. We expect these to be in place by July 2014. We will then also initiate a process for all existing customers to apply again for a new agreement. This will be using a revised data sharing agreement, which will be designed to ensure that all parties have absolute clarity on their obligations with regards to the use of the data and the required controls
- The Data Access Advisory Group (DAAG) will now provide independent scrutiny and review of applications, prior to making a recommendation to approve or reject an application. Requests for new data and requests for amendments to existing agreements that require additional data items will be processed following the successful processing of all other renewals.

We are also currently enhancing our audit capability by developing a function that in future will undertake audits of adherence to obligations within data sharing agreements, including security of data and the deletion of physical and logical data at the end of agreements.

Given the large number of agreements that exist, the process of taking all customers through the re-application process will take a number of months. However, we will work with you in a pragmatic manner during this time, and will continue to use short-term renewals as appropriate.

Should you wish to request an extension to the term of the existing agreement, please notify us in writing at enquiries@hscic.gov.uk.

If your agreement has expired, and you do not wish to request an extension, under the terms of the agreement you are obliged to ensure that:

Health and Social Care Information Centre
1 Trevelyan Square
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Leeds
LS1 6AE

Tel: 0845 300 6016

enquiries@hscic.gov.uk
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- Any data held is permanently deleted;
- Physical media is destroyed using a high specification shredder with the functionality to irreversibly destroy the disc;
- Any data held is also permanently deleted from any backup tapes that contain it;
- You confirm in writing to us that all data has been destroyed / deleted securely in accordance with the terms of your agreement.

While I recognise that this introduces some significant challenge for yourselves, I am sure you will agree that all of us need to work together to increase, rather than dissipate, public trust. Without public confidence it becomes impossible to deliver the full benefits from the analysis and insight which data can deliver. Thank you in advance for your cooperation in this extremely important matter. I will write again when we have further detail to share about proposed changes to applications.

If you wish to have a discussion about any of the points raised in this letter, please contact enquiries@hscic.gov.uk alternatively call 0845 300 6016 selecting option 2.

Yours sincerely

Max Jones
Director of Information and Analytics
Health and Social Care Information Centre

Henson, Lesley

From: Enquiries CRM [enquiries@hscic.gov.uk]
Sent: 21 August 2014 12:23
To: Henson, Lesley
Subject: Ref: NIC-261255-H2N1L Your Enquiry - Complaint - Application for linked HES-ONS data - Regarding NIC-223311-Z0B8Q

Ref: NIC-261255-H2N1L

Dear Lesley,

Further to our recent phone conversation in relation to your enquiry

Please see the response below from our Data Linkage Team:

Dear Dr Henson,

I write in response to your complaint about the service you received in relation to your application for linked HES-ONS data.

There are several factors that have contributed to the delays you have experienced. Having reviewed this case, I can see that Richard Webster had progressed your applicat on as far as he could and was waiting on approval being given by another party, at which point the HSCIC commenced a review of all of its policies ir relation to data release which resulted in major changes to previous processes. Aside from an initial lengthy delay while this review took place, the outcomes of the review necessitated further work to a large number of existing cases in order to submit them via the new processes and your application was put into a queue awaiting that work. The information and timescales communicated by Richard prior to that point were reflective of the process at that time but became subsequently inaccurate because of the changes to procedures.

I fully acknowledge that communication around these developments since the start of the review has not been good enough and I apologise for the significant inconvenience this has caused you.

I have assigned your case to Helen Buckels who is currently reviewing it to establish the required steps to facilitate approval under the new procedures. Helen will manage your case through to completion and will be responsible for keeping you updated on progress and timescales going forward. You should expect to hear from Helen shortly.

Kind Regards,

Carmen Pinder

Contact Centre Team
Health and Social Care Information Centre
1 Trevelyan Square
Boar Lane
Leeds
LS1 6AE

0845 300 6016
Email: enquiries@hscic.gov.uk
http://www.hscic.gov.uk

1

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Tel: 0845 300 6016
Fax: 0113 254 7299

enquiries@hscic.gov.uk
www.hscic.gov.uk

22 September 2014

Kings College London

Dear Lesley Henson,

HSCIC Enquiry Ref: NIC- 223311-Z0B8Q

Your application for HES data was submitted to the Data Access Advisory Group (DAAG) and was considered for approval on 9th September 2014.

The DAAG members were content to recommend approval for your application for HES data.

I am pleased to advise that I have accepted the recommendation to approve your application.

Please note that this approval is subject to your compliance to the terms and conditions as set out in the Agreement provided to you for access to the data.

We would remind you that approval has been given based on the purpose stated within your application. Any change to that purpose, including the data (or products derived from that data) being utilised for any commercial use except where specifically identified and referenced within the Agreement, is not permitted without a resubmission and specific approval by HSCIC.

If you have any queries relating to this approval, please contact the Data Access and Information Sharing Team at (dais@hscic.gov.uk).

Yours sincerely,

Rob Shaw
Director of Operations and Assurance Services & SIRO
Health and Social Care Information Centre

hscic Health & Social Care Information Centre

Bespoke Data Re-Use Agreement (Extracts)

IC Ref: NIC-223311-Z0B8Q

1.0 Organisations

This **Data Re-Use Agreement** (the Agreement) is drawn up between:

Health & Social Care Information Centre (HSCIC)
1 Trevelyan Square
Boar Lane
Leeds
LS1 6AE

And:

King's College London (the "Licensee")
Department of Palliative Care
Policy and Rehabilitation
Cicely Saunders Institute
Bessemer Road
London
SE5 9PJ

This Agreement grants to the **Licensee** a time limited licence to re-use the data defined in Section 3 of this agreement. The data must only be used in accordance with the terms set out in this agreement and as additionally contained in the Standard Terms and Conditions for the Use and Re-Use of Public Sector Information, (Version 2.2 attached) and as may be additionally specified in Section 5 below.

This licence is limited to granting the **Licensee** rights to utilise the data in products or services supplied by you for,

Academic Research herein-after **the "Field" in,**

England herein-after **the "Territory".**

Together the term Field and Territory represent the permissible **"Market"** for your products and services in accordance with our Standard Terms and Conditions for the Use and Re-Use of Public Sector Information, (Version 2.2 attached). Should you require

a license or licenses for additional markets, please contact **the HSCIC** to discuss the terms and conditions on which such additional licenses might be granted.
In case of doubt, the Terms and Conditions set out in this Re-Use Agreement shall take precedence over any corresponding Terms and Conditions contained in subsidiary documents referenced herein.

2.0 Period of agreement

This agreement commences on **1st October 2014** and will will terminate or be extended prior to **30th April 2015.**

3.0 Data required

Pseudonymised records extracted from the following databases:

- HES Admitted Patient Care - **data years of 2010-2011 to 2011-2012**
- HES Accident & Emergency - **data years of 2010-2011 to 2011-2012**
- ONS Mortality Data

3.1 Specification

Data to be supplied as per the Data Specification in Appendix A. Please check the Data Specification and sign to confirm the required data.

3.2 Permissions

Approved Researcher Accreditation for ONS Mortality data.
DAAG recommendation for approval - SIRO recommendation letter dated 22ND September 2014.

4.0 Purpose for which data is to be used

Re-Use Application Statement

The data will be used to describe trends in use of emergency department attendance and identify factors associated with emergency department use based on cancer type and proximity to death.

Study aim:

- *to explore the factors associated with, and impact of, UK ED attendance in patients with advanced cancer.*

Objectives:

- *To determine what symptoms cause adult patients with advanced cancer to present to the emergency department*
- *To determine the clinical diagnosis made for adult patients with advanced cancer who present to the emergency department*
- *To describe the outcomes of patients with advanced cancer who present to the emergency department, including length of hospital stay in those patients admitted, place of discharge, place of death, and procedures and investigations performed*
- *To describe how the above factors are affected by cancer type*
- *To describe how the above factors are affected by stage of disease*

Based on your Extract Application statement(above), the HSCIC grants to **Licensee** a non-exclusive licence to use or re-use the data specified in section 3 above for the following purposes:

- Use only within the Field and Territory as specified in this Agreement.
- Publishing the material in any medium, including featuring the information asset on websites which can be accessed via the Internet or via an internal electronic network or on an Intranet.
- ~~Authorising users and subscribers who use the Licensee's electronic or digital products to access the material.~~
- ~~Translating the information asset into another language or converting to Braille or other formats for people who are visually impaired.~~

5.0 Specific Conditions

5.1 **Licensee** warrants that it and named users of this dataset agree to comply with the principles of **the HSCIC HES Analysis Guide** (November 2012), and **the NHS Care Record Guarantee** before using this data.

5.2 Any data or information provided which is designated "Pre-Publication" or 'Pre-Release" is subject to the additional terms and conditions contained in our ***Special Terms and Conditions for Pre-Release Access to Official Statistics***.

5.3 The National Statistician will set standards for protecting confidentiality, including a guarantee that no statistics will be produced that are likely to identify an

individual unless specifically agreed with them, where the guarantee is judged against the standard that 'it would take a disproportionate amount of time, effort and expertise for an intruder to identify a statistical unit to others, or to reveal information about that unit which is not already in the public domain. Consequently any publication[1] derived from this data by any party are subject to ONS confidentiality guidance on the release of Health Statistics.

5.4 This guidance is provided in the Confidentiality Guidance document and associated working papers to be found at:

ONS Guidance for Health Statistics
http://www.ons.gov.uk/ons/guide-method/best-practice/disclosure-control-of-health-statistics/index.html

ONS policy on protecting confidentiality within birth and death statistics and the Code of Practice for Official Statistics.
http://www.ons.gov.uk/ons/guide-method/best-practice/disclosure-control-policy-for-birth-and-death-statistics/index.html

5.5 Specifically, **Licensee** undertakes to ensure that appropriate controls are in place, to ensure compliance with the HSCIC ***Small Numbers Special Terms and Conditions***. Such controls will, as a minimum, meet the requirements of condition 3.3 of the Small Numbers Special Terms and Conditions and more generally satisfy Section 5 of the ONS confidentiality guidance.

5.6 Before undertaking publication activity, **Licensee** or ***any other party*** using this dataset or any derived information will undertake an organisational Risk Assessment Exercise to ensure compliance with the above guidelines.

5.7 Any publications derived from this Data by any party must be subject to the following guidance:
Anonymisation Standard for Publishing Health and Social Care Data:
http://www.isb.nhs.uk/library/standard/128

The HSCIC retains copyright of this information and this must be cited correctly as follows:

"Copyright © 2013, Re-used with the permission of the Health & Social Care Information Centre. All rights reserved."

5.8 Extension of the period of agreement will be subject to formal review by the HSCIC.

[1] In the context of this Agreement the term "Publication" or "Publications" has the same definition as in the Re-Use of Public Sector Information Regulations 2005

6.0 Specific Exclusions

No part of this dataset may be shared with any third party in the format in which it is provided to you by the HSCIC.

Other than specified in this Agreement, no part, derivative, or analysis produced using the data specified in section 3 may be sold, traded or otherwise used in any commercial or economic activity without the express authorisation of the Health & Social Care Information Centre, such agreement not to be unreasonably withheld subject to payment of the appropriate licence fees.

7.0 Charges

7.1 This request has been categorised as **Market 2, Type B** in accordance with our Standard Terms and Conditions for the Use and Re-Use of Public Sector Information Typology Annex 1. In accordance with this policy the following charges are deemed to apply based on the anticipated sales by period of 12 months:

(i) Re- Use Licence Fee –

a. Admitted Patient Care Annual Licence **£ZERO**

b. Accident & Emergency Annual Licence **£ZERO**

(ii) Service Production **Fee – £2,162;** which for the avoidance of doubt contains 6% Return on Investment elements. This is comprised of:

a. *£630 new service set-up fee*

b. *£318 additional fee for ONS approval (charged per approval/renewal)*

c. *£652 HES dataset extraction charge*

d. *£262 ONS dataset extraction charge*

e. *£300 Annual service charge (charged if the extract is deemed sensitive or includes personal confidential information)*

7.2 The charges set out above are payable in accordance with condition 9 of our Standard Terms and Conditions for the Re-Use of Public Sector Information, on the following Due Date **– 30 days of the receipt of the HES data extract.**

7.3 All charges are subject to the prevailing rate of VAT at the point of invoicing other than those customers who are part of the NHS VAT group.

8.0 Data sharing

No individual other than those named in this agreement can access the dataset and the dataset must only be used for the explicit purpose set out above. In case of staff changes, the **Licensee** will inform the HSCIC of these changes prior to new staff members gaining access to the dataset listed in this agreement.

Named individual to have access	Organisation
Lesley Henson	*King's College London*
Gao Wei	*King's College London*
Irene Higginson	*King's College London*

The users below will have access to the pseudonymised HES records only –

Named individual to have access	Organisation
Barbara Daveson	*King's College London*

9.0 User Obligations

9.1 The HSCIC formally wishes to acknowledge its explicit commitment to maintaining the confidentiality, safety, security and integrity of all confidential and sensitive Data to which the organisation is privy and which may be held under its guardianship.

The HSCIC continues to legitimately enter into formal agreement and/or implicit undertaking with all its clients, staff, visitors, suppliers and others, in recognition of the fact that the Data is held under the guardianship of the HSCIC and which is pertinent to the individual client, staff member, visitor, supplier and/or other, will only be used for the explicit agreed purpose or purposes for which it has been provided, and that there will be no unlawful disclosure or loss of the same.

Users of the Data supplied are obliged to fully comply with The Data Protection Act 1998, together with all other related and relevant legislation and Department of Health directives covering issues of Data sharing and including:

- British (International) Standard ISO 27001;
- The Caldicott Report 1997;
- The Freedom of Information Act 2000;
- Section 251 of the Health and Social Care Act 2006;
- Confidentiality: NHS Code of Practice 2003;
- NHS Records Management Code of Practice (Part 1, 2006 & Part 2, 2009);
- The NHS Information Security Management Code of Practice 2007;
- The Computer Misuse Act 1990;

- The Electronic Communications Act 2000;
- The Regulation of Investigatory Powers Act 2000:
- The Copyright, Designs and Patents Act 1988;
- The Re-Use of Public Sector Information Regulations 2005;
- The Human Rights Act 1998
- The NHS Care Record Guarantee 2007
- Anonymisation Standard for Publishing Health and Social Care Data

9.2 Your extract may contain small numbers, by signing this document you are confirming that you understand and agree to the guidelines set out by the HES Analysis Guide (section 6). The HES Analysis Guide strictly prohibits the release of small numbers meeting certain criteria, no persons other than those named in this DRA have permission to view such small numbers and the data should be suppressed accordingly before it is shared with any other parties. ADHERENCE TO THE HES ANALYSIS GUIDE IS MANDATORY, IT CAN BE VIEWED AT: http://www.hscic.gov.uk/media/1592/HES-analysis-guide/pdf/hes-analy-guide-apr13.pdf

10.0 Audit

During the period of this agreement the HSCIC reserves the right to undertake an audit of **Licensee** to ensure that all terms of this agreement are being abided by.

11.0 Transfer of data from HSCIC to LICENSEE

- The data is categorised as **Sensitive** and will be treated by the HSCIC in accordance with the HSCIC protocols for the transfer and use of NHS **Sensitive** Data.
- Unless otherwise agreed the form of data transfer will be by Secure Electronic File Transfer (SEFT).
- Before transfer the HSCIC will create a profile on SEFT for the named person taking responsibility within this agreement. The password will have length of 12 which MUST include numbers, letters and symbols, and should be a mix of UPPER and lower case characters.
- The password will be provided to the named person taking responsibility within this agreement at **King's College London** via telephone or e-mail. Once the HSCIC is satisfied that the password has been received safely, the information will be sent.
- The named person must NOT share the data or password with any other person at any time.

12.0 Storage of Data

In signing this agreement, the **Licensee** will ensure that the supplied data will be stored on a secure system password protected where by access to the HES data is restricted to only those who are named within this agreement.

13.0 Data Retention

The supplied data will be retained by **Licensee** until the date agreed with the HSCIC. If data is required for longer, approval from The HSCIC will be obtained.

14.0 Data Destruction

In signing this agreement, the **Licensee** will ensure that the supplied data will be securely destroyed using file shredding software. Similarly, physical media will be destroyed using a high specification shredder with the functionality to irreversibly destroy the disc. The data will also be removed from any back up tapes that contain it. Confirmation that this has occurred will be given in writing to the HSCIC.

15.0 Breach of Conditions

Notification of breach The Licensee agrees to report immediately to the HSCIC instances of breach of any of the terms of this Agreement.

Right to terminate access The breach of any of the terms of this Agreement may result in the immediate termination of access to the data and the return of the data to the HSCIC in the manner to be advised by the HSCIC.

Sanctions The breach of any of the provisions of this Agreement may result in sanctions being sought against the Licensee.

16.0 Changes to Terms of Agreement

The HSCIC has the right to change the terms of this agreement and these will be notified to the Licensee in writing. On such occasion unless **Licensee** notifies the HSCIC in writing within 14 days of receiving notice of any changes the HSCIC will assume that the agreement will continue under the revised terms.

If the person signing for **Licensee** should leave their post or the responsibility for this agreement changes from them, then it is incumbent on that person to arrange a new signatory to this agreement and the HSCIC informed of this requirement immediately.

Agreement Signatures

By signing this document you are confirming that you understand and agree to the guidelines set out by the HES Analysis Guide.

For and on behalf of:

King's College London

Signed:

Print name:

Post/Title:

Date:

King's College London
Department of Palliative Care
Policy and Rehabilitation
Cicely Saunders Institute
Bessemer Road
London
SE5 9PJ

For and on behalf of:

Health & Social Care Information Centre

Signed:

Print name: **Dean White**

Post/Title: **Head of Commercial Management**

Date:

Health & Social Care Information Centre
1 Trevelyan Square
Boar Lane
Leeds
LS1 6AE

Appendix A: Customer Application – Data Extract Specification

EXTRACT SPECIFICATION – NIC-223311-Z0B8Q
King's College Hospital NHS Foundation Trust

1. Pseudonymisation key

Your pseudonymisation key reference will be provided to you on delivery on your data. This can be used for future requests.

2. Data requested

Dataset	Years
Admitted Patient Care	2010-11 to 2011-12
Accident & Emergency	2010-11 to 2011-12
ONS Mortality	01-04-2011 to 31-03-2012

3. Filters

ONS Filters

CAUSE_OF_DEATH between 'C00' and 'C97'

AND

DOD between '2011-04-01' and '2012-03-31'

APC & A&E

Where HESIDs in ONS data obtained as above.

4. Fields

Admitted Patient Care - from 2010-2011 to 2011-2012 - 156 fields

admincat	bedyear	opdte_nn	pcgcode	respct06	gpprac	postdur	pctorig06
endage	spelbgin	operstat	pctcode	resstha	pconsult	biresus_n	EPIKEY
startage	epiend	posopdur	pctcode06	resstha06	preggmp	sexbaby_n	
neodur	epistart	preopdur	gpprpct	pcttreat	preferer	delstat_n	
mydob	speldur	classpat	procode	rotreat	referorg	neocare	
dob_cfl	spelend	intmanig	procode3	Resro	delprean	wellbaby	
ethnos	epidur	mainspef	procodet	sthatrel	delposan	censage	
encrypted_hesid	epiorder	tretspef	sitetret	soal	antedur	carersi	
postdist	epie_cfl	domproc	protype	soam	birordr_n	detndate	
sex	epis_cfl	hrg_3.5	gppracro	rururb_ind	birweit_n	det_cfl	
admidate	epistat	hrgnhs	gpprstha	imd04c	delchang	cendur	
adm_cfl	epitype	hrgnhsvn	oacode6	imd04ed	delmeth_n	detdur	
elecdate	provspno	suscorehrg	rescty	imd04em	delplac	marstat	
elec_cfl	disreadydate	sushrg	resladst	imd04hd	delinten	mentcat	
admimeth	diag_nn	sushrgvers	resladst_currward	imd04hs	anasdate	admistat	
admisorc	diag3_01	susspellid	ward91	imd04i	anagest	censtat	
firstreg	diag4_01	purcode	resgor	imd04ia	gestat_n	vind	
elecdur	cause	purval	gortreat	imd04ic	birstat_n	cenward	
dischdate	cause4	purro	resha	imd04ie	delonset	subdate	
dis_cfl	cause3	purstha	hatreat	imd04	matage	nhsnotnd	
disdest	oper_nn	csnum	pctnhs	imd04rk	numbaby	opcs43	
dismeth	opertn3_01	gppracha	respct	imd04_decile	numpreg	pctorig	

A & E - from 2010-2011 to 2011-2012 - 87 fields

activage	aedepttype	trettime	oacode6	resro	imd04rk	hrgnhsvn	orgpppid
arrivalage	initdur	conclime	rescty	IMD04HS	soal	sushrg	rttperstart
carersi	tretdur	deptime	currward	imd04c	soam	sushrgvers	rttperstat
ethnos	concldur	diag_n	respct06	imd04_decile	rururb_ind	procode3	rttperend
nhsnoind	depdur	diag2_n	resstha06	imd04ed	gortreat	procode	waitdays
postdist	aeincloctype	diaga_n	ward91	imd04em	hatreat	procodet	gpprac
encrypted_hesid	aepatgroup	diags_n	resgor	imd04hd	pcttreat	pctcode06	preggmp
sex	aerefsource	invest_n	resha	imd04ia	rotreat	pctcode02	perend
aearrivalmode	arrivaldate	invest2_n	respct02	Imd04ic	sthatret	gpprpct	subdate
aeattendcat	arrivaltime	treat_n	resstha02	imd04i	domproc	protype	aekey
aeattenddisp	inittime	treat2_n	resladst	imd04le	hrgnhs	gpprstha	

ONS

Encrypted_HESID
DOD
DOR
RESSTHA
RESPCT
SEX
COMMUNAL_ESTABLISHMENT
NHS_INDICATOR
CAUSE_OF_DEATH
CAUSE_OF_DEATH_NON_NEONATAL_NN
MATCH_RANK
DEATH_RECORD_USED
SUBSEQUENT_ACTIVITY

hscic Health & Social Care Information Centre

5. The extract will be produced in the form of ASCII files, pipe-delimited, unless otherwise stated. Your extract will be compressed using Winzip v14 . Please note that you will require software capable of uncompressing files using this level of encryption. If you are unsure of which version you have please contact your local IT support.

6. Note that the data will not be identical to that received from the data providers. It has been cleaned by the HES system and in some cases, the "unknown" and "inapplicable" values have been changed to conform to the "typing" requirements of the system. The HES data dictionary explains the meaning of the fields, in particular giving the "unknown and "inapplicable" codes for many fields. The HES data dictionary can be accessed via the HES web pages at http://www.hscic.gov.uk/hesdatadictionary

7. Please see the HES data quality notes to assure yourself that your specification will meet your requirements: these can be found on each datasets publication documents on website:
http://www.hscic.gov.uk/hes

8.

9. If you have any queries regarding this data specification or would like to make any amendments then please raise these issues with the HSCIC via data.applications@hscic.gov.uk before returning this document. (Please include your reference number beginning '*NIC*' in the title of any responses)
10. Requests to make amendments to this data specification after the data has been produced will result in additional costs.

Please sign below to confirm that you wish to continue with this data request to receive the data as specified above.

SPECIFICATION AGREED

(Signature)	(Name)	(Date)

Appendix B - Research Ethics Committee Documents for Secondary Data Analysis

HOW TO BECOME AN APPROVED RESEARCHER

Step 1

You first need to contact ONS to explain the purpose of your statistical research and your wish to access its personal information.

To contact ONS about your research use the contact details in the following link and give us a brief indication of what data you hope to use.
http://www.ons.gov.uk/about/who-we-are/our-services/unpublished-data/index.html.

Step 2

We will then send you an application pack to help us decide whether we can grant the access you require. This will include a Declaration and a data access agreement for you to sign and return.

Step 3

Once we have received your completed forms, signed declaration and data access agreement we will decide whether you satisfy the published criteria to grant access to that information and whether the disclosure may be authorised.

Step 4

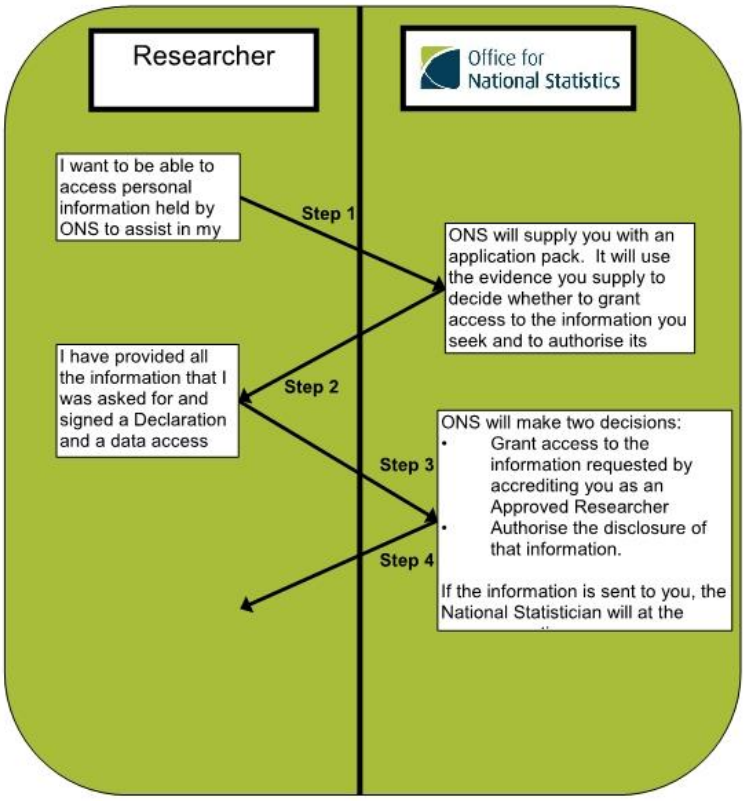
ONS will notify you of the outcome of its decision. If it is necessary to refuse your application then the reasons will be included in a letter.

When you are granted access to the personal information you will also receive a letter from the National Statistician explaining your responsibilities for the security of that information.

ONS aims to process applications to be accredited as an Approved Researcher as quickly as possible and, usually, within three weeks.

Office for National Statistics

HOW TO BECOME AN APPROVED RESEARCHER



Application for Accreditation as an Approved Researcher

The information you provide on this form will used to consider whether you meet the criteria needed to be accredited as an Approved Researcher under the Statistics and Registration Service Act 2007.

An assessment will only be made in relation to a purpose that, in the opinion of the National Statistician, is statistical research that serves the public good.

Criteria against which each application will be considered

A researcher is deemed 'Fit and Proper' when….

The researcher is able to demonstrate, to the satisfaction of the National Statistician, that he/she:

- **Has the appropriate knowledge and experience necessary for handling potentially disclosive personal information;**
- **Has provided satisfactory evidence supporting their application that illustrates their professionalism and technical competence to carry out the research proposal;**
- **Demonstrates a commitment to protecting and maintaining the confidentiality of the data during the creation of outputs and publications that arise during the proposal.**

A research project is deemed suitable when….

The research, in the opinion of the National Statistician, serves one of the following public benefits :

- **Supporting the formulation and development of public policy or public service delivery.**
- **Forms part of the programme of research covered by the National Data Strategy or otherwise supported directly or indirectly by the Economic and Social Research Council.**

3. **Supports an obligation of public law (e.g. Local Development Plans)**

- **Explores new statistical methods that can be used to produce statistics that serve the public good.**

1. Your Details

Your Name	Dr Lesley Henson
Institution or Organisation	King's College London
Address	Department of Palliative Care, Policy and Rehabilitation, Cicely Saunders Institute, Bessemer Road, Denmark Hill, London, SE5 9PJ
Telephone No	020 7848 5689
Email	Lesley.Henson@kcl.ac.uk

2. Describe briefly (in approx. 100 words) the purpose of the proposed research.

- **OPTCare – Optimising palliative care for older people in community settings; development and evaluation of a new short-term integrated service (a joint project between King's College London and Sussex Community NHS Trust) (funder NIHR/CNO clinical lectureship and NIHR Research for Patient Benefit)**
- OPTCare aims to develop and evaluate the feasibility of a new short-term palliative care service for frail elders in community settings delivered through integrated working between specialist palliative care services and community nursing teams, and close working with GPs and geriatricians. The project uses a two-phase design. This application pertains to phase 1a developing the new service. Phase 1 uses a post-bereavement survey (QUALYCare) to examine preferences for care, palliative outcomes and cost-effectiveness for frail elders by place of death. The ONS administered the survey in October 2012 to people who had registered the death of an older person meeting eligibility criteria (n=882, 50.2% response rate single wave with two reminders). The survey closed 28th February 2013. Data entry and cleaning is complete and preliminary descriptive analysis commenced. The findings inform the new service evaluated in phase 2; a comparative feasibility trial funded through an NIHR Research for Patient Benefit grant. Project end date November 2015.

3. Please State the period for which access to personal information is required.

Period for which access to personal information is required	From (10/12/2013)	To (06/11/2015

4. Experience : Outline your experience of research that has involved handling potentially disclosive personal information.

Information and its source	Transcribed interviews with cancer patients and their carers regarding their care experiences and the coordination or care between services.
Research title and date	"An Empirical Model of Care Coordination Involving Advanced Progressive Illness: A Longitudinal Qualitative Study with Patients and Unpaid Caregivers" 2013
Your specific involvement	Qualitative analysis of patient and carer interviews to develop an empirical model as outlined in title above.
Statistical use of the information	Qualitative study with grounded theory approach
Measures used for disclosure control and information security	Data was transcribed verbatim, but annonymised at this time point. It was then held securely with encryption and double locking within the department accessed only by approved researchers working on the project.
Other relevant information	I am training as a PhD student and working closely with three supervisors who have all had extensive experience of working with patient information and the use of research techniques.

Include any other information you feel would help to demonstrate your experience in handling potentially disclosive personal information.)

I have had 8 years working as a medical doctor including the most recent 3 years working in palliative care. I have during that time had access to large amounts of personal patient information and been trained in information governance and the importance of handling patient records appropriately. I have attended numerous courses in statistical analysis of data to provide me with the skills to appropriately analyse datasets. I am also working with and being supervised by an experienced medical statistician throughout my PhD.

The department I am currently working in has an extensive research portfolio and I am learning more about the use of data in a research setting and being closely supervised throughout all stages of my PhD.

I am committed to protecting and maintaining the confidentiality of any data that is provided to me and to comply with all aspects of data handling controls. This commitment will extend to beyond the analysis of the data so that any papers or outputs will consider in their design and publication the issue of patient confidentiality. I have never had any concerns raised regarding my probity or professional conduct with regards to patient/ data confidentiality or other aspects of my work.

5. Professionalism : **Provide membership details of professional bodies.**

A. General Medical Council (GMC # 6120851)
B. Member of the Association of Palliative Medicine
C. Member of the Royal College of Physicians

Provide examples of your contribution towards public policy or journal publications.

A. **Bringing Hope..... EVALUATION OF THE PALLIATIVE CARE PILOT PROJECT; LAKE ZONE, TANZANIA IMPACT ON PATIENTS, THEIR FAMILIES AND CARE GIVERS, AND STAFF; A MODEL OF CHURCH LED INETGRATION July 2012**
B. Jeyakumar J, Fleming J, **Henson L** and Thorns A. (2011 May). **Palliative Care Patients' Attitudes to Participating in Research Trials.** Poster Presentation at the 12th Congress of the European Association for Palliative Care, Lisbon
C. Fleming J, **Henson L**, Jeyakumar J and Cawley D. (2011 May). **A Baseline Review of Prescribing, Documentation and Use of Sedation in 3 Hospice Inpatient Units.** Poster Presentation at the 12th Congress of the European Association for Palliative Care, Lisbon

Include any other information you feel would help to demonstrate your professional competence.

COURSES AND CONFERENCES

June 2011	**The Association for Palliative Medicine: Appraising the literature and Research – getting started** Clifton Hill House, Bristol
May 2011	**12th Congress of the European Association for Palliative Care** Lisbon, Portugal
Jan. 2011	**Key Academic Skills and Preparation for a Career in Academic Medicine** London Deanery
Sept. 2010	**SPR Study Day in Palliative Medicine: Palliative Care for Patients with a Non-malignant Diagnosis** Cicely Saunders Institute, King's College Hospital
July 2010	**SPR Study Day in Palliative Medicine: Palliative Rehabilitation, Survivorship, Dementia & End of Life Care Planning Study Day** Edenhall Hospice, Hampstead
June 2010	**Best Practice Forum: Motor Neurone Disease** Pilgrim's Hospice, Ashford
May 2010	**Advanced Communication Skills Training Course** Tudor Park Hotel, Maidstone
March 2010	**SPR Study Day in Palliative Medicine: Pain update study day** Royal Marsden Hospital, Chelsea

Office for National Statistics

Approved Researcher Access

APPLICATION FORM

Office Use

Continuation Page

This Data Access Approval pertains to Dr Lesley Henson as a PhD research fellow for the study OPTCare – Optimising palliative care for older people in community settings; development and evaluation of a new short-term integrated palliative care service (SIPC) (NIHR/CNO and NIHR Research for Patient Benefit). The study aims to develop and evaluate the feasibility of the new SIPC service for frail elders in community settings (including care homes) delivered through integrated working between specialist palliative care services and community nursing teams, and close working with GPs and geriatricians. The study uses a phased design:

- Phase 1 developing and refining the intervention of SIPC involving:
  - A post-bereavement survey (QUALYCare[1]) administered to carers (n=882) through the ONS using death registration data (50.2% response rate). Following NHS ethical and governance approvals, and ONS approval, the ONS opened the survey in October 2012 and closed in February 2013.
  - Stakeholder consultation on the survey findings to refine the SIPC service involving service providers and commissioners, patients and their families/carers and voluntary sector.
- Phase 2 feasibility evaluation of SIPC service using a comparative trial
  - 52 frail elders meeting eligibility criteria randomised to receive the SIPC service or best usual care. Service delivered through integrated working between two specialist community palliative care teams and four community nursing teams, and close working with GPs and geriatricians.
  - Primary outcome – palliative distress (Integrated-Palliative care Outcome Scale, I-POS).

This Data Access Agreement pertains to the post-bereavement survey to access the ONS dataset for the survey sample. The ONS dataset requested comprises:

- Underlying cause of death
- Second and third underlying causes of death
- Contributing causes of death (up to 15)
- Age of deceased at time of death
- Months from deceased's death to sending questionnaire
- Days from deceased's death to sending questionnaire
- Months from deceased's registered death to receiving the questionnaire
- Days from deceased's registered death to receiving the questionnaire
- Official place of death (this is useful to compare with responses obtained in the questionnaire)
- Official place of death with address (this helps us to check ONS coding and check accuracy, particularly if discrepancies in the data. For example QUALYCare had an address coded as a hospice, but when checked it was a hospital. This clarified a data discrepancy of comparatively high number of hospice deaths at this location).
- Place of birth of deceased (this is useful for comparison between born in UK or overseas)
- Relationship of the informant (person who registered the death) to the deceased
- Gender of the informant
- Index of Multiple Deprivation (IMD) 2010 including: quintiles, overall scores to enable calculation of the means and medians and the composite IMD (education, income etc) to facilitate analysis by socio demographic variables
- Rural and Urban Area Classification (RUAC) 2004 category

The research team involves senior academics with expertise, for example, in statistical analysis of population based surveys (Dr Gao Wei, Prof Irene Higginson) and post-bereavement surveys (Dr Barbara Gomes), population based data sets (Dr Emma Gordon, ONS) and health economic evaluation (Prof Paul McCrone). Gao Wei, Higginson and Gomes hold Data Access Agreements with the ONS. Dr Catherine Evans is PI with Professor Irene Higginson as joint PI. OPTCare is a joint project between King's College London and Sussex Community NHS Trust funded through national research grants.

Office for National Statistics

Approved Researcher Access

DECLARATION

Office Use

Access to personal information as an Approved Researcher is conditional upon signing this Declaration.

By signing this Declaration, you are confirming

- the accuracy of any information you provide to support your application,
- your understanding of the conditions specified below,
- you will abide by any other requirements communicated to you by the National Statistician relating to this use of potentially disclosive personal information.

DECLARATION:

I declare that the personal information provided to me shall be kept secure and confidential according to the terms of any agreements with the Office for National Statistics.

I understand that :

Personal information means information which relates to and identifies a particular person(including a body corporate). Information identifies a particular person if the identity of that person is specified in the information; can be deduced from the information itself; or can be deduced from the information taken with any other published information;

UK Statistics Authority reserves the right to scrutinise any products or publications for disclosure control purposes before publication;

I may be liable to criminal prosecution under the Statistics and Registration Service Act 2007 if I disclose this personal information to any other person without the written authority of the National Statistician or other Member of the UK Statistics Authority;

My lawful use of this information is only for the purposes of statistical research that will serve the public good as agreed in writing with the National Statistician;

I am required to bring directly to the attention of the National Statistician any matters or events that may affect my obligations under this declaration, my Approved Researcher accreditation, or any other matter in the written agreements relating to this use of personal information.

I am authorised to access this personal information only when I receive from the National Statistician or other Member of the UK Statistics Authority a written and signed confirmation, and only until the end date in that written confirmation.

Signed:

Print Name: Lesley Henson Date:28th August 2014

Office for National Statistics

Approved Researcher Access APPLICATION FORM

COMPLETION NOTES

Office Use

COMPLETION NOTES

General

Accreditation as an Approved Researcher provides a temporary lawful authority under the Statistics and Registration Service Act 2007 (the Act) which allows the use of a particular set of personal information held by the UK Statistics Authority for a stated piece of statistical research. You should note that you will also have to satisfy other requirements (such as the suitability of your processing environment) before you will be authorised by the National Statistician to receive any information.

When completing the forms, you should focus on providing evidence that will enable the National Statistician to reach a decision that the Approved Researcher criteria have been met and that access to the information should be provided for the purpose specified.

You are not compelled to complete every section of the form as long as the evidence you provide is sufficient to demonstrate that you are a fit and proper person under the Act.

If the evidence you provide is found to be insufficient we will give you the opportunity to add to it. If you are still unsuccessful you will be provided with details of a review process to which you may apply. Your declaration will be considered void if your application is not successful.

The completed form, and any other information used by the National Statistician, may be made public, if, for example, to do so is necessary to assure the public or Parliament about the safeguarding of personal information. Any personal information you send us about yourself will only be used in connection with this application.

- **Your details**

These details will be used to enable ONS to contact you. If you are working as part of an organisation, such as a business, university or charity, please complete the details of that organisation. If you are researcher not affiliated to any particular employer the details are likely to be your personal ones and you should write 'None' next to Institution. Contractors should apply as individuals in their own right.

2. **Describe briefly (in approx. 100 words) the purpose of the proposed research.**

The purpose for which the data are required must be statistical, and should be the focus of the research and resultant analysis. The prime focus for accessing the data should not be for the purpose of personal or commercial gain. The purpose should be one that serves the 'public good'.

Office for National Statistics

Approved Researcher Access APPLICATION FORM

COMPLETION NOTES

Office Use

3. **Please State the period for which access to personal information is required.**

Under the Act access can only be given for a specified period of time. Please ensure that you state an appropriate period of time as any access outside these dates may be a breach of the Act making you liable to prosecution. In the event of unforeseen circumstances the National Statistician may extend the period at a later date.

4. **Experience :**

You should outline your experience of research that has involved handling potentially disclosive personal information.

Any details you provide should focus on relevant experience and should illustrate your suitability to use personal information.

5. **Professionalism :**

Provide membership details of professional bodies

Membership of professional bodies can include associations or societies. Current details are of more interest but you may provide details of past memberships where you consider them appropriate.

Provide examples of your contribution towards public policy or journal publications.

Include details of publications that provide evidence of your meeting the published criteria. Electronic links would be helpful.

6. **Any further information for consideration.**

If you fear that your application is insufficient when matched against one or more criteria then use this space to add any extra evidence you feel is relevant. If you have only limited evidence you should provide the name of a suitable referee. You must include any evidence which is relevant in any way. Remember there is a more detailed written agreement where the details and benefits of the research can be set out.

Office for National Statistics

Approved Researcher Access APPLICATION FORM

COMPLETION NOTES

Office Use

Glossary of Terms

TERM	DEFINITION
1 Personal information	'personal information' is defined in section 39(2) of the 2007 Act as 'information which relates to and identifies a particular person (including a body corporate);' [See point 3 below]
2 Fit and proper person	A fit and proper person is one who is able to demonstrate, to the satisfaction of the UKSA, that he/she: 1.1 has the appropriate knowledge and experience necessary for handling confidential personal information. 1.2 has provided satisfactory evidence to support their application that adequately illustrates their professionalism and technical competence to use the data requested in the research proposal 1.3 is committed to protecting and maintaining the confidentiality of the data and their technical and physical security, during their use of the data and the creation of outputs and publications arising from their analyses.
3 Confidential	Confidential 'personal information' is information 3.1 that specifies the identity of a particular person (including a body corporate) 3.2 from which the identity of a particular person can be deduced, or 3.3 from which the identity of a particular person can be deduced when taken together with other published information

Office for National Statistics

Approved Researcher Access APPLICATION FORM

COMPLETION NOTES

Office Use

Glossary of Terms

TERM	DEFINITION
4 Public good	Research that informs 'the public about social and economic matters, and assists in the development and evaluation of public policy' (section 7 of the 2007 Act). It is research that: 1.1 produces statistics that describe as accurately as possible the developments in the economic, social, environmental and cultural spheres (Commission of the European Communities) 1.2 builds the information capacity required to sustain strategic objectives and the underlying policies and supporting instruments (Commission of the European Communities) 1.3 informs debate, decision making and research both within government and by the wider community (United Nations Economic Commission for Europe (UNECE) Conference of European Statisticians: Managing Statistical Confidentiality & Microdata: Principles and Guidelines of Good Practice) 1.4 provides an objective perspective of the changes taking place in national life and allow comparisons between periods of time and geographical areas (UNECE: Principles and Guidelines of Good Practice) 1.5 'offers a window on the work and performance of government itself, showing the scale of government activity in every area of public policy and allowing the impact of public policies and actions to be assessed' (UNECE: Principles and Guidelines of Good Practice) 1.6 assists the Government in its work

QUALYCARE study confidentiality agreement

This Agreement between the QUALYCARE Team, King's College London, Department of Palliative Care, Policy & Rehabilitation, Cicely Saunders Institute, Bessemer Road, London SE5 9PJ and Dr Lesley Henson is effective as of 22nd August 2014.

Dr Lesley Henson (The "Recipient") agrees to keep confidential and to use only for the purposes of discussions with members of the QUALYCARE research team, her PhD project and publications approved by the QUALYCARE study Principal Investigator (Prof Irene Higginson), any information relating to the QUALYCARE study the Recipient may receive from the QUALYCARE team.

Dr Lesley Henson (The "Recipient") agrees to handle any information related to the QUALYCARE study in full compliance with the procedures specified in the QUALYCARE study ethics application and subsequent amendments, approved by King's College Hospital Research Ethics Committee (REC ref no.: 09/H0808/85).

The obligation to keep information confidential shall not apply to;
(a) Information which the Recipient knows or possesses already as such or which, through independent research or investigation, becomes known to the Recipient without reference to information supplied under this agreement,
(b) Information which as such is publicly known at the time of its disclosure or which becomes known later through no fault of the Recipient, or
(c) Information belonging to a third party and disclosed lawfully to the Recipient by the third party.

Intellectual property relating to information disclosed under this agreement will remain with the disclosing party, and the Recipient has no authority to apply for any patent or other registered form of intellectual property in anything based on or obtained from the information.

This Agreement shall commence on the date given above and shall remain in force for the duration of the QUALYCARE study and for five years following completion of the QUALYCARE study.

Should the terms of this Agreement at any time be contravened, breached or infringed, by the Recipient, the Recipient may be liable to the disclosing party for damages in respect of any such breach.

This Agreement shall be governed by and construed in accordance with the laws of England and Wales and subject to the jurisdiction of the English courts.

Signed for agreement on behalf of the QUALYCARE team

.....

Name: Prof Irene Higginson
Title: QUALYCARE Principal Investigator
Date: 22/08/14

Signed for agreement on behalf of Dr Lesley Henson

.....

Name: LESLEY HENSON
Title: CICELY SAUNDERS INTERNATIONAL PHD CLINICAL TRAINING FELLOW
Date: 22/08/14

School of Medicine
at Guy's, King's College and St Thomas' Hospitals

Department of Palliative Care, Policy & Rehabilitation

Professor Irene Higginson
BMedSci BMBS FFPHM PhD FRCP
Head of Department
Professor Lynne Turner-Stokes
DM FRCP
Herbert Dunhill
Chair of Rehabilitation

Cicely Saunders Institute
Bessemer Road
Denmark Hill
London SE5 9PJ
Tel: +44 (0)20 7848 5516
Fax: +44 (0)20 7848 5517
www.kcl.ac.uk/palliative

KING'S College LONDON

Professor Irene J Higginson
Professor of Palliative Care, Policy and Rehabilitation
Dr Barbara Daveson
IARE Research Fellow
IARE Principal Investigator

Stephanie Hill, NRES (REC) Coordinator
NHS Health Research Authority
NRES Committee London Dulwich
Room 4W/12, 4th Floor
Charing Cross Hospital
Fulham Palace Road
London W6 8RF

22/04/2014

Dear Stephanie,

Reference: 12/LO/0044 – The IARE Study

Full title of the study: The International Access, Rights and Empowerment Study: an international mixed methods study to compare palliative care experiences among older people affected by cancer and non cancer conditions

We would like to propose a minor amendment to the postal follow-back survey for work package three (carer study). This concerns the addition of another researcher who is already working on the project that IARE forms part of, BuildCARE project. Dr Lesley Henson will be joining the research team from April 28th 2014 and performing some additional analysis on the accident and emergency data received from the follow-back surveys and possibly data from WP1 and WP2 as well in order to achieve the overall aim of the project, which is to improve the access and rights of those to palliative care. We are hoping to explore this additional analysis as our recent systematic review has shown that palliative care access is associated with emergency department use by patients with advanced cancer at the end of life.

We trust this minor amendment is acceptable to the committee; this analysis is in keeping with the consent that we have gained from all participants and is in line with our current research aims and objectives. It will also ensure that we use the data to its full potential. I look forward to receiving your response regarding this and please do let me know if you require any further information.

Yours sincerely,

Professor Irene Higginson
Chief Investigator
Professor of Palliative Care, Policy and Rehabilitation

King's College London
Department of Palliative Care, Policy and Rehabilitation
Cicely Saunders Institute
6 Bessemer Road, SE5 9PJ, London

Dr Barbara Daveson
Principal Investigator
Cicely Saunders International Lecturer in Health Services Research

cc. Melinda Smith, IARE Research Assistant
Will Bowen, R&D Facilitator

School of Medicine
at Guy's, King's College and St Thomas' Hospitals

Department of Palliative Care, Policy & Rehabilitation

Professor Irene Higginson
BMedSci BMBS FFPHM PhD FRCP
Head of Department
Professor Lynne Turner-Stokes
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KING'S College LONDON

Professor Irene J Higginson
Professor of Palliative Care, Policy and Rehabilitation
Dr Barbara Daveson
IARE Research Fellow
IARE Principal Investigator

Will Bowen, R&D Facilitator
Research and Development Department
First Floor
Jennie Lee House
King's College Hospital NHS Foundation Trust
34 Love Walk
Denmark Hill
London SE5 8AD

22/04/2014

Dear Will Bowen,

Reference: 12/LO/0044 – The IARE Study

Full title of the study: The International Access, Rights and Empowerment Study: an international mixed methods study to compare palliative care experiences among older people affected by cancer and non cancer conditions

We would like to propose a minor amendment to the postal follow-back survey for work package three (carer study). This concerns the addition of another researcher who is already working on the project that IARE forms part of, BuildCARE project. Dr Lesley Henson will be joining the research team from April 28th 2014 and performing some additional analysis on the accident and emergency data received from the follow-back surveys and possibly data from WP1 and WP2 as well in order to achieve the overall aim of the project, which is to improve the access and rights of those to palliative care. We are hoping to explore this additional analysis as our recent systematic review has shown that palliative care access is associated with emergency department use by patients with advanced cancer at the end of life.

We trust this minor amendment is acceptable to the committee; this analysis is in keeping with the consent that we have gained from all participants and is in line with our current research aims and objectives. It will also ensure that we use the data to its full potential. I look forward to receiving your response regarding this and please do let me know if you require any further information.

Yours sincerely,

Professor Irene Higginson
Chief investigator
Professor of Palliative Care, Policy and Rehabilitation

King's College London
Department of Palliative Care, Policy and Rehabilitation
Cicely Saunders Institute
6 Bessemer Road, SE5 9PJ, London

Dr Barbara Daveson
Principal investigator
Cicely Saunders International Lecturer in Health Services Research

cc. Melinda Smith, IARE Research Assistant
Stephanie Hill, NRES (REC) Coordinator

Appendix C - Ethics Approval Letter for Analysis of Linked ONS HES Data

05/12/2013

King's College Hospital NHS
NHS Foundation Trust

Dr Lesley Henson
Cicely Saunders Institute
Bessemer Road
London
SE5 9PJ

King's College Hospital NHS Foundation Trust
King's College Hospital
Denmark Hill
London SE5 9RS

Tel: 020 3299 9000
Fax: 020 3299 3445
Minicom: 020 3299 9009
www.kch.nhs.uk

Direct tel: 020 32991981
Direct fax: 020 3299 5515
Email: kch-tr.research@.nhs.net

RE: Emergency department attendance by cancer patients towards the EOL (1)

Dear Dr Henson

Thank you for approaching the R&D Department with your IRAS form. After reviewing your form I can confirm that your project will not require Research Ethics Committee or Research & Development approval.

Analysis of routinely collected clinical data does not require either REC or R&D approval so long as the data are fully anonymous.

Please don't hesitate to get in contact if you require any further clarification.

Regards

Will Bowen
Research Facilitator
The Research Office
1st Floor 161 Denmark Hill
London SE5 8EF

Appendix D - Qualitative Interview Study Research Ethics Committee Application Form and Approval Documents

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please enter a short title for this project (maximum 70 characters)
Emergency Department Attendance by Patients with Advanced Cancer (v1)

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product
( ) Clinical investigation or other study of a medical device
( ) Combined trial of an investigational medicinal product and an investigational medical device
( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
( ) Basic science study involving procedures with human participants
( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
(●) Study involving qualitative methods only
( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
( ) Study limited to working with data (specific project only)
( ) Research tissue bank
( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation?	( ) Yes	(●) No
b) Will you be taking new human tissue samples (or other human biological samples)?	( ) Yes	(●) No
c) Will you be using existing human tissue samples (or other human biological samples)?	( ) Yes	(●) No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

[x] England
[ ] Scotland
[ ] Wales
[ ] Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please enter a short title for this project (maximum 70 characters)
Emergency Department Attendance by Patients with Advanced Cancer (v1)

1. Is your project research?

◉ Yes ○ No

2. Select one category from the list below:

○ Clinical trial of an investigational medicinal product
○ Clinical investigation or other study of a medical device
○ Combined trial of an investigational medicinal product and an investigational medical device
○ Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
○ Basic science study involving procedures with human participants
○ Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
◉ Study involving qualitative methods only
○ Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
○ Study limited to working with data (specific project only)
○ Research tissue bank
○ Research database

If your work does not fit any of these categories, select the option below:

○ Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation?	○ Yes	◉ No
b) Will you be taking new human tissue samples (or other human biological samples)?	○ Yes	◉ No
c) Will you be using existing human tissue samples (or other human biological samples)?	○ Yes	◉ No

3. In which countries of the UK will the research sites be located?*(Tick all that apply)*

☑ England
☐ Scotland
☐ Wales
☐ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

◉ England
○ Scotland
○ Wales
○ Northern Ireland
○ This study does not involve the NHS

4. Which review bodies are you applying to?

☑ NHS/HSC Research and Development offices
☐ Social Care Research Ethics Committee
☑ Research Ethics Committee
☐ National Information Governance Board for Health and Social Care (NIGB)
☐ National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D offices, the CI must create Site-Specific Information Forms for each site, in addition to the study-wide forms, and transfer them to the PIs or local collaborators.

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

◉ Yes ○ No

Please describe briefly the involvement of the student(s):
This research project is being undertaken as part of a PhD programme at King's College London.

Dr Lesley Henson (PhD student) will be involved in the design, recruitment and undertaking of the research project. Dr Henson is being supervised by Dr Barbara Daveson, Dr Gao Wei and Professor Irene Higginson, who are all based at the Department of Palliative Care, Policy & Rehabilitation, King's College London. Dr Henson receives structured PhD supervision on a fortnightly basis, and has access to additional support from supervisors in-between these times as required.

This research study will form part of a Dr Henson's overall PhD thesis which is exploring emergency department attendance by patients with advanced cancer towards the end of life.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

◉ Yes ○ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

Integrated Research Application System
Application Form for Research involving qualitative methods only

NHS
Health Research Authority

Application to NHS/HSC Research Ethics Committee

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Emergency Department Attendance by Patients with Advanced Cancer (v1)

Please complete these details after you have booked the REC application for review.

REC Name:
NRES committee south central - Berkshire

REC Reference Number:
14/SC/1207

Submission date:

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

How do patients with advanced cancer decide to attend the emergency department, and what influences their decision-making at this time? A qualitative case study

A2-1. Educational projects

Name and contact details of student(s):

Student 1

	Title	Forename/Initials	Surname
	Dr	Lesley A	Henson
Address	King's College London, Cicely Saunders Institute		
	Department of Palliative Care, Policy & Rehabilitation		
	Bessemer Road		
Post Code	SE5 9PJ		
E-mail	lesley.henson@kcl.ac.uk		
Telephone	02078485689		
Fax	02078485517		

Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/ degree:
PhD in Palliative Care

Name of educational establishment:
King's College London

Name and contact details of academic supervisor(s):

Academic supervisor 1

	Title	Forename/Initials	Surname
	Dr	Barbara A	Daveson
Address	King's College London, Cicely Saunders Institute		
	Department of Palliative Care, Policy & Rehabilitation		
	Bessemer Road		
Post Code	SE5 9PJ		
E-mail	barbara.daveson@kcl.ac.uk		
Telephone	02078485565		
Fax	02078485517		

Academic supervisor 2

	Title	Forename/Initials	Surname
	Dr	Wei	Gao
Address	King's College London, Cicely Saunders Institute		
	Department of Palliative Care, Policy & Rehabilitation		
	Bessemer Road		
Post Code	SE5 9PJ		
E-mail	wei.gao@kcl.ac.uk		
Telephone	02078485570		
Fax	02078485517		

Academic supervisor 3

	Title	Forename/Initials	Surname
	Prof	Irene J	Higginson
Address	King's College London, Cicely Saunders Institute		
	Department of Palliative Care, Policy & Rehabilitation		
	Bessemer Road		
Post Code	SE5 9PJ		
E-mail	irene.higginson@kcl.ac.uk		
Telephone	02078485516		
Fax	02078485517		

Please state which academic supervisor(s) has responsibility for which student(s):
Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

Student(s)	Academic supervisor(s)
Student 1 Dr Lesley A Henson	☑ Dr Barbara A Daveson

☑ Dr Wei Gao

☑ Prof Irene J Higginson

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

○ Student
◉ Academic supervisor
○ Other

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Dr	Barbara A	Daveson
Post	Cicely Saunders International Lecturer in Health Services Research in Palliative Care		
Qualifications	PhD, BMus (MUSTHY)		
Employer	King's College London		
Work Address	Cicely Saunders Institute		
	Department of Palliative Care, Policy & Rehabilitation		
	Bessemer Road		
Post Code	SE5 9PJ		
Work E-mail	barbara.daveson@kcl.ac.uk		
* Personal E-mail			
Work Telephone	02078485565		
* Personal Telephone/Mobile			
Fax	02078485517		

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
	Mr	Keith	Brennan
Address	Room 1.8, Hodgkin Building		
	King's College London, Guy's Campus		
	Great Maze Pond, London		
Post Code	SE1 4UL		
E-mail	keith.brennan@kcl.ac.uk		
Telephone	02078486960		
Fax	02078486394		

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):

Sponsor's/protocol number:

Protocol Version:

Protocol Date:

Funder's reference number:

Project website:

Additional reference number(s):

Ref.Number Description	Reference Number

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

(●) Yes ( ) No

Please give brief details and reference numbers.
This study is part of a broader programme of international palliative care research, project BuildCARE, which includes 'The International Access, Rights and Empowerment Study: an international mixed methods study to compare palliative care experiences among older people affected by cancer and non cancer conditions' (REC reference: 12/LO/0044).

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, this summary will be published on the website of the National Research Ethics Service following the ethical review.*

Background
Many people living with advanced cancer visit the emergency department near the end of life. Often these visits are associated with poor outcomes such as prolonged pain and overall dissatisfaction. However, despite these negative outcomes emergency department visits by advanced cancer patients are increasing. Most of the literature investigating this topic has focused on quantifying emergency department attendance and describing variations in emergency department use according to different patient and environmental factors. Much less is known about why patients attend the emergency department and what factors influence their decision at this time.

Aim
To investigate the processes by which advanced cancer patients and their caregivers decide to attend the emergency department, and to explore advanced cancer patients' and their caregivers' preferences for an urgent care service.

Objectives:
1. To explore how demographic, clinical and environmental factors influence advanced cancer patients' and their caregivers' decision to attend the emergency department.
2. To describe the relationship between demographic, clinical, environmental, and any other factor(s) identified.
3. To explore what alternatives were considered by advanced cancer patients and their caregivers when deciding to attend the emergency department.
4. To describe and explore advanced cancer patients' and their caregivers' preferences for an urgent care service.

Design
Based at King's College Hospital, this qualitative case-based study will involve interviews with patients and their caregivers, and review of patients' healthcare records. Interviews will take approximately one hour during which

participants will be asked about a recent decision to attend the emergency department and the factors that influenced this decision.

Outcome
Study findings will improve our understanding of the needs and preferences of advanced cancer patients requiring urgent care, and assist in the development of a community screeing tool that can help healthcare professionals identify patients at high-risk of overly aggressive end of life care, such as multiple emergency department visits.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, R&D office or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

WHY IS THIS STUDY IMPORTANT?

Most patients with cancer prefer to be cared for at home, especially towards the end of life (1-4). However, despite these preferences an estimated 30-40% of cancer patients attend the emergency department during the last month of life (5, 6). Often these visits are associated with poor outcomes such as prolonged pain and overall patient and caregiver dissatisfaction (7).

Most of the scientific literature regarding advanced cancer patients use of the emergency department has focused on quantifying emergency department attendance and/ or statistically describing emergency department use according to various individual and/ or environmental factors. Much less is known about why cancer patients attend the emergency department and what factors influence their decision-making process.

In order to investigate these research questions further the present study aims to investigate the processes by which advanced cancer patients, and their caregivers, decide to attend the emergency department, and; to explore advanced cancer patients', and their caregivers', preferences for an urgent care service.

RECRUITMENT

HOW WILL PATIENTS BE RECRUITED TO TAKE PART IN THE STUDY?

Recruitment to the study will be over a six month period. All potential patient participants will be identified through the acute oncology and palliative care teams based at King's College Hospital. From the date of study commencement, a clinical member from each team (acute oncology and palliative care), will screen all new referrals received against the study inclusion/ exclusion criteria.

Eligible patients identified will first be approached by a clinical member of the acute oncology or palliative care team (dependent on which team the patient is under) within 2 weeks of their presentaion to the emergency department. Potential participants will not be approached whilst in the emergency department. When first approached, the clinical team member will introduce the study, explain that participation is entirely voluntary, and provide the patient with an information leaflet about the study. Patients will mostly be approached whilst in hospital (if admitted from the emergency department), however, if a potentially eligible patient has been discharged directly from the emergency department the clinical team member will telephone them at home regarding the study and their potential involvement.

Only patients who express an interest in the research and who are agreeable to meeting with a member of the research team will have their names passed on to the research team (such details will be shared weekly at a meeting between clinical and research team members). For these patients, Dr Lesley Henson (PhD clinical training fellow), or another member of the research team (including clinical research nurses), will follow-up the initial contact and be available to explain the study in detail, answer questions and address any concerns.

For patients who would like to participate, and after a minimum of 24 hours from first contact with a member of the research team, informed written consent to conduct an in-depth qualitative interview, and for a member of the research team to access the patients' healthcare records will be obtained by Dr Henson, or another member of the research team (including clinical research nurses). A minimum period of 24 hours between full explanation of the study and completion of the consent form will be advised for all participants in order to provide an opportunity for patients to reflect on the study and their involvement. If, after 24 hours, potential patient participants would like additional time to consider their involvement a future meeting time will be organised.

Some potential participants may feel that they do not require 24 hours to consider their involvement, and are comfortable to consent, or decline, earlier than this, for example some soon-to-be discharged patients may prefer to be interviewed before leaving hospital. In these situations the researcher will be guided by the patients' preferences for consenting.

HOW WILL CAREGIVERS BE RECRUITED TO TAKE PART IN THE STUDY?

Eligible caregivers will be identified through patients recruited to the study, who will be asked if they have a caregiver. Eligible caregivers will therefore not be screened by the clinical palliative care or acute oncology teams. As caregivers may not be known to any particular healthcare team, they will first be approached by a member of the research team. For patients with a caregiver, consent will be sought from the patient for Dr Henson, or another member of the research team (including clinical research nurses) to contact the patients' caregiver regarding participation in the study. Only patients who provide informed consent for Dr Henson, or another member of the research team (including clinical research nurses) to approach their caregiver about the study will be contacted.

Where consent is provided, Dr Henson, or another member of the research team (including clinical research nurses) will contact the caregiver and introduce herself and the study. It will be explained that participation is entirely voluntary, and potential caregiver participants will be provided with an information leaflet about the study. After this initial contact potential caregiver participants will be given at least 24 hours to reflect on the study and consider their involvement. Dr Henson, or another member of the research team (including clinical research nurses) will then follow-up this initial contact and be available to answer questions, address any concerns, and ascertain the caregivers' interest in participating. If, after 24 hours, potential caregiver participants would like additional time to consider their involvement a future meeting time will be organised.

Some potential participants may feel that they do not require 24 hours to consider their involvement, and are comfortable to consent, or decline, earlier than this. In these situations the researcher will be guided by the caregivers' preferences for consenting.

WILL EVERY PATIENT WITH ADVANCED CANCER WHO ATTENDS THE EMERGENCY DEPARTMENT BE ABLE TO PARTICIPATE?

This study is interested in exploring the processes by which patients with advanced cancer, and their caregivers, decide to attend the emergency department. In order to explore this topic adequately patients brought to the emergency department by a third party will be excluded, i.e. patients brought to the emergency department by representatives of Her Majesty's Prison Service and under their supervision, and patients attending the emergency department from nursing homes, care homes, hospices or other institutionalised care settings.

Participants who are incapable of providing informed consent will be excluded from the study. It is expected that this will include a cohort of cancer patients who attend the emergency department very close to the end of life, and/ or are unable to provide informed consent due to the severity of their disease. Patients will also be excluded if the clinical teams responsible for their care consider them to be too unwell and/ or distressed to participate in the study.

CONSENT

All potential participants will have the study explained to them (initially by a clinical member of the palliative care or acute oncology team) and be provided with an information leaflet outlining the purpose of the study and including details of what participation would involve. An in-depth further explanation of the study will be given by Dr Henson, or another member of the research team (including clinical research nurses) from the research team. Adequate time will be given for participants to read the study information leaflet (minimum of 24 hours) and ask Dr Henson any further questions about the study.

Once someone has decided that they would like to participate, they will be required to fully comprehend the risks, benefits and burden of their taking part, and give written informed consent to do so. Dr Henson, or another member of the research team (including clinical research nurses), who are trained and experienced in the consent process, will be responsible for obtaining consent from all participants. All members of the research team have completed Good Clinical Practice training at Kings College London.

Patients with advanced cancer can experience episodes of cognitive impairment and/ or sudden deteriorations in their overall health. Dr Henson is trained and experienced in assessing patients for cognitive impairment. This experience includes four years working as a palliative care physician. Dr Henson will assess the cognition of all patients prior to the consent process and again prior to the interview according to best practice guidelines (8). If a patient is found to have impaired cognition and/ or there is a sudden clinical deterioration, which impairs their ability to provide informed consent, the participant will be excluded from the study and the clinical team caring for the patient informed of the findings to ensure optimal medical management is administered. Any information that has been collected during the research process will be confidentially destroyed.

For any participant that decides to withdraw from the study no further data will be accessed or collected from the point of withdrawal onwards. Any prior data collected with consent will either be confidentially destroyed, or kept and included in the study analysis, depending on the preference of the participant. However, once data has been aggregated at the analysis stage of the study, withdrawal of individual patient information will no longer be possible. This will be explained during the consent process to all potential participants and is included in the participant information leaflets (version 1, 30.07.14).

ARE THERE ANY RISKS TO PARTICIPANTS SURROUNDING THIS STUDY, AND WHAT STEPS HAVE BEEN TAKEN TO PREVENT THIS?

There is a substantial and growing body of evidence, including two systematic reviews, describing the benefits of participating in research for individuals with life-limiting diseases (9, 10). However, despite these benefits, there is small risk that in-depth research interviews may uncover new or inadequately managed health and/ or psychosocial concerns. Some participants may also find elements of the interview process distressing.

Both the study's principle investigator, Dr Barbara Daveson, all academic supervisors, and the doctoral student, Dr Lesley Henson, have experience in conducting research with palliative care patients. Dr Henson, who will be completing the study interviews, is experienced in working with vulnerable patients and their families, and in March 2014 completed Good Clinical Practice training at King's College London.

In the unlikely event that distress is experienced druing the interview or because of it, a distress protocol, which has been developed based on those successfully used by researchers in the Department of Palliative Care, Policy & Rehabilitation for previous studies where qualitative interviews were conducted, will be used. During the interview process there will be ongoing monitoring for any indications of distress, both actively with frequent verbal checks that the participant is okay and would like to continue, as well as non-verbal indicators that may suggest the participant is distressed such as a change in the level of engagement with the interview or appearing nervous/ anxious. Breaks will be used should participants become distressed and the interview will be terminated early if required. Any participant who is distressed will be offered additional support from the research team and the wider cancer support community, for example Macmillan support centre details will be provided, in accordance with the distress protocol.

It will be explained to all participants that they have the option of withdrawing from the study at any time and for any reason. Participants will also be advised that they do not need to answer every interview question, and can come back to questions at a later stage in the interview process if they wish.

All data collected will remain strictly confidential unless any unsafe practice is revealed, i.e. information that represents a risk to the participant, others, and/ or is required to be disclosed by law. In this situation confidentiality will be breached and the participant will be informed of this. Information will then be reported following local guidelines, as well as being discussed with the research and clinical team leads to ensure safe and best practice is maintained. This is indicated in the participant information leaflet (version 1, 30.07.14).

As with any research project there are risks related to data protection and security. To address these risks all data collected will be anonymised and stored on an encrypted, password-protected external hard drive, which when not in use, will be kept in a locked filing cabinet, in a secure office, within the Department of Palliative Care, Policy and Rehabilitation, King's College London. Study participants will be assigned a unique identifier (code number) at the time of data collection. These codes will only be linked to person identifiable information in a research 'code book' which will be kept in a separate locked cabinet and away from any copies of the data itself. All data protection requirements will be fulfilled.

REFERENCES

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8.
2) Brogaard T, Neergaard MA, Sokolowski I, Olesen F, Jensen AB. Congruence between preferred and actual place of care and death among Danish cancer patients. Palliative medicine. 2013 Feb;27(2):155-64. PubMed PMID: WOS:000314469800008. English.
9.
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10.
4) Higginson IJ, Sen-Gupta GJ. Place of care in advanced cancer: a qualitative systematic literature review of patient preferences. Journal of palliative medicine. 2000 Fall;3(3):287-300. PubMed PMID: 15859670.
5) Huang J, Boyd C, Tyldesley S, Zhang-Salomons J, Groome PA, Mackillop WJ. Time spent in hospital in the last six months of life in patients who died of cancer in Ontario. J Clin Oncol. 2002 Mar 15;20(6):1584-92. PubMed PMID: 11896108.

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3) Matthews FE, Stephan BC, Khaw KT, et al. Full-scale scores of the Mini Mental State Examination can be generated from an abbreviated version. Journal of clinical epidemiology 2011; 64(9): 1005-13.
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10) White C, Hardy J. What do palliative care patients and their relatives think about research in palliative care?-a systematic review. Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer. 2010 Aug;18(8):905-11. PubMed PMID: 19705165.

A6-3. Proportionate review of REC application *The initial project filter has identified that your study may be suitable for proportionate review by a REC sub-committee. Please consult the current guidance notes from NRES and indicate whether you wish to apply through the proportionate review service or, taking into account your answer to A6-2, you consider there are ethical issues that require consideration at a full REC meeting.*

○ Yes - proportionate review ◉ No - review by full REC meeting

Further comments (optional):

Note: This question only applies to the REC application.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply*:

- [x] Case series/ case note review
- [ ] Case control
- [ ] Cohort observation
- [ ] Controlled trial without randomisation
- [ ] Cross-sectional study
- [ ] Database analysis
- [ ] Epidemiology
- [ ] Feasibility/ pilot study
- [ ] Laboratory study
- [ ] Metanalysis
- [x] Qualitative research
- [x] Questionnaire, interview or observation study
- [ ] Randomised controlled trial
- [ ] Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

The purpose of this study is to investigate the processes by which advanced cancer patients and their caregivers decide to attend the emergency department, and to explore advanced cancer patients' and their caregivers' preferences for an urgent care service.

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

Study Objectives

1. To explore how demographic, clinical and environmental factors influence advanced cancer patients' and their caregivers' decision to attend the emergency department.

2. To describe the relationship between demographic, clinical, environmental, and any other factor(s) identified.

3. To explore what alternatives were considered by advanced cancer patients and their caregivers when deciding to attend the emergency department.

4. To describe and explore advanced cancer patients' and their caregivers' preferences for an urgent care service.

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

Between 2001 and 2020 the annual incidence of cancer cases in England is predicted to rise 33%, from 224,000 in 2001 to 299,000 by 2020, mostly due to the anticipated effects of population growth and ageing (1). In addition to this there is evidence that end of life cancer care is becoming increasingly aggressive as reflected by greater numbers of emergency department attendances, intensive care unit admissions and use of chemotherapeutic agents towards the end of life (2-4). At present an estimated 20% of the National Health Service (NHS) budget is spent on care for those in the last year of life (5) with many of the additional costs seen attributable to an increased use of acute care services such as unplanned hospital admissions and emergency department attendances (6).

Most patients with advanced cancer prefer to be cared for, and die, at home (7, 8). In addition to these preferences, the emergency department is often an unsuitable place for patients with advanced cancer to receive high-quality acute care. Emergency department environments are typically hectic and practical issues such as risk of exposure to infection makes them unsatisfactory for many advanced cancer patients who are often immunocompromised through their advanced disease state and/ or treatment. Emergency department overcrowding continues to be a problem despite evidence showing its association with an increased risk of poor patient outcomes such as prolonged pain and overall patient dissatisfaction (9, 10). Continuity of care is lost with presentation to the emergency department, something valued by patients with cancer who would prefer direct admission to an oncology unit, or treatment at home, if given the choice (11, 12). Studies also suggest that many emergency department physicians feel under-qualified when treating patients near the end of life who typically have complex medical conditions and extensive care needs that have historically not been part of emergency physician specialist training (13-16).

In 2003, Earle and colleagues identified the prevalence of emergency department attendance in the last 30 days of life as one potential indicator of end of life cancer care quality (17). This was during a time when, in an attempt to reduce overall emergency department attendance, many NHS immediate care services were experiencing substantial change, including the creation of new GP walk-in centres, telephone advice services and extended healthcare practitioner roles (18-21). Yet, despite these initiatives, and recognition of the problems associated with emergency department use towards the end of life, emergency department attendance in the general and advanced cancer populations has continued to rise, suggesting that the needs and/ or preferences of many patients, and/ or their caregivers, are not being fully addressed through these additional measures (2, 21).

Healthcare professionals and patients can judge the severity and urgency of clinical conditions very differently (22). Many of the previously implemented healthcare services that aimed to reduce emergency department attendance have since been criticised for failing to incorporate the thoughts and opinions of service-users when being developed (21, 23, 24). Through their experience and expert knowledge, service-users can provide valuable perspectives that often "challenge traditional assumptions" (Husband, 2010, page 5)(25), and allow for development and delivery of services that are likely to be more effective, deliver better care outcomes, and provide greater overall patient satisfaction (26).

In 2012-13, 64.1% of all emergency department attendances in England were self-referrals (27). In the palliative care population self-referrals are estimated to be between 26-40% (28, 29). With NHS care widely available and free at the point of access, any future interventions aiming to reduce emergency department utilisation, in order to be successful, need to consider patients, and their caregivers, self-perceived needs, and understand the processes by which patients decide to attend the emergency department (21, 23, 30).

Most of the scientific literature regarding advanced cancer patients' use of the emergency department has focused on quantifying emergency department attendance and/ or statistically describing emergency department use according to various individual and/ or environmental factors. Much less is known about why such variations exist, and how the various factors associated with emergency department attendance influence utilisation.

The present study aims to address these important issues by investigating advanced cancer patients reason(s) for attending the emergency department, and by further exploring the factors that influence their decision-making. Findings generated will assist in the development of a community screening tool that can help healthcare professionals identify patients at high-risk of overly aggressive care towards the end of life, such as multiple emergency department visits.

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A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

STUDY DESIGN

Qualitative studies allow in-depth investigation and exploration of topics, and can be often help answer study questions that are not able to be studied using a quantitative approach.

The present study aims to explore the phenomenon of decision-making within the specific context of patients with a diagnosis of advanced cancer and in need of urgent care. A collective (multiple) case-based design has been chosen as this approach places emphasis on the social context and can be approprite when the topic being studied cannot be observed such as with decision-making. It is also an appropriate approach for situations where the context is complex and involves "many variables that would not realistically be able to be explored with quantitative or alternative methods" (Walshe, 2008, page 138)(1). Case-based research utilises multiple sources of data which when converged enhance the overall understanding of the study topic and assist in understanding complexity. For this study the unit of analysis ("case") will be an instance of decision-making by a patient with advanced cancer to attend the emergency department. Data will be collected from patients, caregivers, and healthcare records, using the following methods of data collection:
1. semi-structured interviews with patients
2. semi-structured interviews with caregivers
3. review of patients' healthcare records

METHODOLOGY

The study will be conducted at King's College Hospital (KCH) NHS Foundation Trust, south-east London. A purposive sampling strategy, maximum variation (heterogeneity) sampling, will be used to select a diverse range of participants. Areas of participant diversity will include patients of varying age, ethnicity, gender and socio-economic status. Patients with a range of cancer diagnoses will also be sampled. This approach aims to provide an in-depth understanding about a phenomenon such as emergency department use "by capturing and describing the central themes that cut across a great deal of variation" (Patton, M.Q., 1990, page 235)(2).

ELIGIBILITY CRITERIA

Patient Inclusion Criteria:
• Adults (≥18 years).
• Diagnosed with advanced cancer by a qualified healthcare professional, e.g. doctor, involved in the patients' care. Advanced cancer defined as cancer that has invaded surrounding body tissues and/ or metastasised and is not curable and is life-threatening (3, 4).
• Assessed as being in one of the following phases of illness by a qualified healthcare professional: "Unstable", "Deteriorating" or "Terminal". Phase of illness will be defined according to the Palliative Care Outcomes Collaboration (PCOC) assessment toolkit that defines unstable as "The person experiences the development of a new unexpected problem or a rapid increase in the severity of existing problems, either of which require an urgent change in management or
emergency treatment". Deteriorating is defined as "The person experiences a gradual worsening of existing symptoms or the development of new but expected problems. These require the application of specific plans of care and regular review but
not urgent or emergency treatment", and Terminal is defined as "Death is likely in a matter of days and no acute

intervention is planned or required. The use of frequent, usually daily, interventions aimed at physical, emotional and spiritual issues is required." (5).
• Have attended, from their private residence, the emergency department at King's College Hospital within two weeks of screening for the study.

Caregiver Inclusion Criteria:
• Adults (≥18 years).
• Identified as a caregiver by an eligible patient recruited to the study. Caregiver defined as an unpaid family member, or close friend, involved in caring for the patients' physical, emotional and/ or practical needs (6).

Patient and Caregiver Exclusion Criteria:

• Children or adolesents (<18 years).
• Participants incapable of providing informed consent, including those with cognitive impairment. Cognitive impairment will be determined at the participant screening stage and again prior to the interview using capacity assessment procedures as per best practice guidelines and legislative requirements (7).
• Patients brought to the emergency department by representatives of Her Majesty's Prison Service and under their supervision.
• Patients attending the emergency department from nursing homes, care homes, hospices or other institutionalised care settings. This is because the focus of this study is on exploring the decision-making process of patients and their unpaid caregivers only. Where there is likely to have been significant involvement by healthcare professionals regarding emergency department attendance, such as with residents of institutionalised care settings, the decision-making process is hypothesised to be very different and therefore would require exploration in its own right.
• Patients whose clinical team consider them to be too unwell and/ or distressed to participate in the study.

RECRUITMENT PROCESS: PATIENTS

Recruitment to the study will be over a six month period. All potential patient participants will be identified through the acute oncology and palliative care teams based at King's College Hospital. From the date of study commencement, a clinical member from each team (acute oncology and palliative care), will screen all new referrals received against the study inclusion/ exclusion criteria.

Eligible patients identified will first be approached by a clinical member of the acute oncology or palliative care team (dependent on which team the patient is under) within 2 weeks of their presentaion to the emergency department. Potential participants will not be approached whilst in the emergency department. When first approached, the clinical team member will introduce the study, explain that participation is entirely voluntary, and provide the patient with an information leaflet about the study (patient participant information leaflet, version 1, 30.07.14). Patients will mostly be approached whilst in hospital (if admitted from the emergency department), however, if a potentially eligible patient has been discharged directly from the emergency department the clinical team member will telephone them at home regarding the study and their potential involvement.

Only patients who express an interest in the research and who are agreeable to meeting with a member of the research team will have their names passed on to the research team (such details will be shared weekly at a meeting between clinical and research team members). For these patients, Dr Lesley Henson (PhD clinical training fellow), or another member of the research team (including clinical research nurses), will follow-up the initial contact and be available to explain the study in detail, answer questions and address any concerns.

For patients who would like to participate, and after a minimum of 24 hours from first contact with a member of the research team, informed written consent to conduct an in-depth qualitative interview, and for a member of the research team to access the patients' healthcare records will be obtained by Dr Henson, or another member of the research team (including clinical research nurses). A minimum period of 24 hours between full explanation of the study and completion of the consent form will be advised for all participants in order to provide an opportunity for patients to reflect on the study and their involvement. If, after 24 hours, potential patient participants would like additional time to consider their involvement a future meeting time will be organised.

Some potential participants may feel that they do not require 24 hours to consider their involvement, and are comfortable to consent, or decline, earlier than this, for example some soon-to-be discharged patients may prefer to be interviewed before leaving hospital. In these situations the researcher will be guided by the patients' preferences for consenting.

RECRUITMENT PROCESS: CAREGIVERS

Eligible caregivers will be identified through patients recruited to the study, who will be asked if they have a caregiver. Eligible caregivers will therefore not be screened by the clinical palliative care or acute oncology teams. As caregivers may not be known to any particular healthcare team, they will first be approached by a member of the research team.

For patients with a caregiver, consent will be sought from the patient for Dr Henson, or another member of the research team (including clinical research nurses) to contact the patients' caregiver regarding participation in the study. Only patients who provide informed consent for Dr Henson, or another member of the research team (including clinical research nurses) to approach their caregiver about the study will be contacted.

Where consent is provided, Dr Henson, or another member of the research team (including clinical research nurses) will contact the caregiver and introduce herself and the study. It will be explained that participation is entirely voluntary, and potential caregiver participants will be provided with an information leaflet about the study (caregiver participant information leaflet, version 1, 30.07.14). After this initial contact potential caregiver participants will be given at least 24 hours to reflect on the study and consider their involvement. Dr Henson, or another member of the research team (including clinical research nurses) will then follow-up this initial contact and be available to answer questions, address any concerns, and ascertain the caregivers' interest in participating. If, after 24 hours, potential caregiver participants would like additional time to consider their involvement a future meeting time will be organised.

Some potential participants may feel that they do not require 24 hours to consider their involvement, and are comfortable to consent, or decline, earlier than this. In these situations the researcher will be guided by the caregivers' preferences for consenting.

INTERVIEWS

Patients and caregivers recruited to the study will be interviewed regarding their recent emergency department attendance and how the decision to attend came about. Interviews will occur separately with patients and caregivers (unless they are not agreeable to this, in which case a joint interview will be conducted). All interviews will be audio recorded and are expected to take approximately 60 minutes. Interviews will take place within one month of the patients' emergency department attendance and will be conducted in a place agreeable to the participant and researcher. This is most likely to be at the participants' home or in a quiet area in the hospital. No future follow-up after the study interview is planned.

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A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- [x] Design of the research
- [x] Management of the research
- [ ] Undertaking the research
- [ ] Analysis of results
- [x] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.
Members of 'The South East London Consumer Research Panel for Cancer' have been consulted regarding this study. Panel members are cancer patients, and/ or their caregivers, who have had experience of clinical trial research, and/ or are interested in research in general. They advise researchers at all stages of the research process by providing written feedback, and/ or direct verbal feedback in one of their quarterly meetings. All members receive regular training on various research issues (for example, the informed consent process) to help maintain an effective

balance between understanding the researchers' requirements and highlighting public interests from research. For the present study 'The South East London Consumer Research Panel for Cancer' have assisted in the overall study design and methodology. In particular members of the group stressed the importance of interviewing caregivers as well as patients when considering the study and also felt that interviews would be the most appropriate method of collecting such data. Members of the group have also provided feedback on the participant information leaflets developed.

Further service-user involvement regarding the study's recruitment process has been sought through the Department of Palliative Care, Policy & Rehabilitation's 'Dissemination, Engagement and Empowerment Advisory Group' which meets quarterly.

Ongoing involvement and collaboration with both groups is planned, particularly regarding dissemination of study findings.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

Patient Inclusion Criteria:
• Adults (≥18 years).
• Diagnosed with advanced cancer by a qualified healthcare professional, e.g. doctor, involved in the patients' care. Advanced cancer defined as cancer that has invaded surrounding body tissues and/ or metastasised and is not curable and is life-threatening (1, 2).
• Assessed as being in one of the following phases of illness by a qualified healthcare professional: “Unstable”, “Deteriorating” or “Terminal”. Phase of illness will be defined according to the Palliative Care Outcomes Collaboration (PCOC) assessment toolkit that defines unstable as "The person experiences the development of a new unexpected problem or a rapid increase in the severity of existing problems, either of which require an urgent change in management or
emergency treatment". Deteriorating is defined as "The person experiences a gradual worsening of existing symptoms or the development of new but expected problems. These require the application of specific plans of care and regular review but
not urgent or emergency treatment", and Terminal is defined as "Death is likely in a matter of days and no acute intervention is planned or required. The use of frequent, usually daily, interventions aimed at physical, emotional and spiritual issues is required." (3).
• Have attended, from their private residence, the emergency department at King’s College Hospital within two weeks of screening for the study.

Caregiver Inclusion Criteria:
• Adults (≥18 years).
• Identified as a caregiver by an eligible patient recruited to the study. Caregiver defined as an unpaid family member, or close friend, involved in caring for the patients’ physical, emotional and/ or practical needs (4).

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A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

Patient and Caregiver Exclusion Criteria:
• Children or Adolesents (<18 years).
• Participants incapable of providing informed consent, including those with cognitive impairment. Cognitive impairment will be determined at the participant screening stage and again prior to the interview using capacity assessment procedures as per best practice guidelines and legislative requirements (1).

• Patients brought to the emergency department by representatives of Her Majesty's Prison Service and under their supervision.
• Patients attending the emergency department from nursing homes, care homes, hospices or other institutionalised care settings. This is because the focus of this study is on exploring the decision-making process of patients and their unpaid caregivers only. Where there is likely to have been significant involvement by healthcare professionals regarding emergency department attendance, such as with residents of institutionalised care settings, the decision-making process is hypothesised to be very different and therefore would require exploration in its own right.
• Patients whose clinical team consider them to be too unwell and/ or distressed to participate in the study.

REFERENCE
1) Matthews FE, Stephan BC, Khaw KT, Hayat S, Luben R, Bhaniani A, et al. Full-scale scores of the Mini Mental State Examination can be generated from an abbreviated version. Journal of clinical epidemiology. 2011 Sep;64(9):1005-13. PubMed PMID: 21411287.

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Seeking consent	1	0	30 mins	Dr Lesley Henson (PhD clinical training fellow)or another member of the research team (including clinical research nurses). Consenting will be completed in a place agreeable to both the participant and researcher.
In-depth, face-to-face qualitative interviews	1	0	60 mins	Dr Lesley Henson (PhD clinical training fellow)or another member of the research team (including clinical research nurses). Interviews will be completed in a place agreeable to both the participant and researcher.

A21. How long do you expect each participant to be in the study in total?

Study participants will be interviewed once only, with each interview expected to take approximately 60 minutes. Time from consent to completion of participant interview is expected to be less than one month. No future contact is planned after completion of interview.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

The proposed study involves neither invasive procedures nor novel therapeutic interventions, and taking part will not affect the participants' medical management in any way. However, despite this there is small risk that in-depth research interviews may uncover new or inadequately managed health and/ or psychosocial concerns. Some participants may also find elements of the interview process distressing.

Both the study's principle investigator, Dr Barbara Daveson, all academic supervisors, and the doctoral student, Dr Lesley Henson, have experience in conducting research with palliative care patients. Dr Henson, who will be completing the study interviews, is experienced in working with vulnerable patients and their families, and in March 2014 completed Good Clinical Practice training at King's College London.

In the unlikely event that distress is experienced druing the interview or because of it, a distress protocol, which has been developed based on those successfully used by researchers in the Department of Palliative Care, Policy &

Rehabilitation for previous studies where qualitative interviews were conducted, will be used. During the interview process there will be ongoing monitoring for any indications of distress, both actively with frequent verbal checks that the participant is okay and would like to continue, as well as non-verbal indicators that may suggest the participant is distressed such as a change in the level of engagement with the interview or appearing nervous/ anxious. Breaks will be used should participants become distressed and the interview will be terminated early if required. Any participant who is distressed will be offered additional support from the research team and the wider cancer support community, for example Macmillan support centre details will be provided, in accordance with the distress protocol.

It will be explained to all participants that they have the option of withdrawing from the study at any time and for any reason. Participants will also be advised that they do not need to answer every interview question, and can come back to questions at a later stage in the interview process if they wish.

All data collected will remain strictly confidential unless any unsafe practice is revealed, i.e. information that represents a risk to the participant, others, and/ or is required to be disclosed by law. In this situation confidentiality will be breached and the participant will be informed of this. Information will then be reported following local guidelines, as well as being discussed with the research and clinical team leads to ensure safe and best practice is maintained. This is indicated in the participant information leaflet (version 1, 30.07.14).

As with any research project there are risks related to data protection and security. To address these risks all data collected will be anonymised and stored on an encrypted, password-protected external hard drive, which when not in use, will be kept in a locked filing cabinet, in a secure office, within the Department of Palliative Care, Policy and Rehabilitation, King's College London. All data protection requirements will be fulfilled. The code book will be kept separately (and securely) to the anonymised data.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

(●) Yes ( ) No

If Yes, please give details of procedures in place to deal with these issues:

The proposed study interviews are not expected to cause any significant distress. However, due to the nature of the research topic, potentially upsetting discussions, in particular regarding the end of life, may occur.

Dr Lesley Henson (PhD clinical training fellow), who will be conducting the study interviews, is trained and experienced in working with vulnerable patients and their families. Dr Henson has worked as a palliative care physician for 4 years and has experience of caring for cancer patients at the end of life and their families. Dr Henson also has experience of conducting qualitative interviews with palliative care patients and their families, and has completed training in advanced communication skills.

All participants will have the option of withdrawing from the study at any time and for any reason. Participants will also be advised that they do not need to answer every interview question, and can come back to questions at a later stage in the interview process, if they wish.

All data will remain strictly confidential unless any unsafe practice is revealed, i.e. information that represents a risk to the participant, others, and/ or is required to be disclosed by law. In this situation confidentiality will be breached and participants will be informed of this. Information will then be reported following local guidelines, as well as being discussed with the research and clinical team leads to ensure safe and best practice is maintained. This is indicated in the participant information leaflets (patient and caregiver participant information leaflets, version 1, 30.07.14).

A24. What is the potential for benefit to research participants?

There is a substantial and growing body of evidence, including two systematic reviews, suggesting that patients and caregivers experience benefit from participating in research (1, 2). Qualitative studies of terminally ill patients' experiences of research have highlighted themes of benefit through social interaction and information provision (3) as well as enhanced problem-solving skills, better coping mechanisms and feelings of empowerment, support and reassurance (4). Studies have also found that research participants often value the opportunity to contribute to research that might help others, and can gain a sense of "usefulness" from participating in research despite their underlying diagnosis.

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A26. What are the potential risks for the researchers themselves? *(if any)*

Exploring emotional topics and/ or dealing with distressed participants can lead to distress within the research team. Dr Lesley Henson (PhD clinical training fellow), who will be conducting the study interviews, will have support throughout the study from the project steering group with which she has regular contact. As part of her PhD training, Dr Henson also has regular structured meetings with her academic supervisors. At the time of this submission these supervision sessions were occurring fortnightly, with no plans to change.

Peer support is also provided through the Department of Pallitive Care, Policy & Rehabilitation's PhD support group. Dr Lesley Henson is a member of this support group and attends meetings monthly.

Completion of study interviews may require research team members to visit participants in the community, for example, at the participant's home. All staff working off-site in this way are required to complete a log showing where they are going to conduct an interview. Researchers will also be paired with a "partner" to ensure that a named individual within the department knows their whereabouts at all times. When off-site conducting research, the research team member will ensure that their partner has their mobile contact number. The research team member will call their partner before and at the end of the interview when they have left the participant. The partner will be aware of expected timings for this and if they do not receive contact will ensure contact is made and that the researcher is safe.

In addition to a "buddy", one of Dr Henson's supervisors will be available by telephone whilst an interview is being conducted in case of any unforeseen problems arising or to discuss any situations where the distress protocol is required.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used?*For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

IDENTIFICATION OF POTENTIAL PATIENT PARTICIPANTS

All potential patient participants will be identified through the acute oncology team or the palliative care team at King's College Hospital (KCH).

The acute oncology service at KCH provides care and advice to hospital in-patients who have been admitted with acute complications from their oncological disease and/ or treatment. They also assess any patients newly diagnosed with cancer during their hospital admission, and assist in their ongoing disease management. The team consists of doctors and specialist nurses and referrals are received from all teams and departments across the hospital via the electronic patient record (EPR) system. In addition to these referrals the team's clinical nurse specialist routinely scans all emergency department visits and the patient lists of the three admission wards at KCH for any additional patients known to oncology, who have not been referred, and may benefit from oncology input during their hospital stay.

Established in 1995, the palliative care team at KCH includes doctors, specialist nurses, social workers and an administration team, which together provide 24-hour care to patients across KCH with serious and/ or life-limiting illnesses. Referrals to palliative care can be made by any member of the patients' clinical team via the hospital's EPR system. Patients referred and identified as having specialist palliative care needs remain under the direct care of their relevant ward team, with the palliative care team providing a specialist advisory service that includes support and

advice on symptom management and information on social, practical and financial issues.

From the date of study commencement, a clinical member from each team (acute oncology and palliative care), will screen all new referrals received against the study's inclusion/ exclusion criteria in order to identify potential patient participants. This study has been discussed with both clinical teams who have agreed to assist with the screenign process and are engageed in the research project.

IDENTIFICATION OF POTENTIAL CAREGIVER PARTICIPANTS

Potential caregiver participants will be identified through consenting patients recruited to the study, and therefore will not be screened for.

IDENTIFICATION OF PATIENTS' HEALTHCARE RECORDS

The healthcare records of consenting patients recruited to the study will be accessed for the two weeks prior and two weeks following their emergency department visit. During the recruitment process patient consent will be specifically sought for a member of the research team to access their healthcare records and only where consent is obtained will the records be viewed. Healthcare records will not therefore be screened for or accessed by any research team member without patients' written informed consent.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

◉ Yes ○ No

Please give details below:
Potential patient participants will be identified by a clinical member of the acute oncology or palliative care team (dependent on which team the patient is under). The clinical team member will be responsible for screening all new referrals received against the study's inclusion/ exclusion criteria. This will involve acccessing basic demographic and clinical information about the patient. The information required for the screening process is typical of the information provided to the clinical team as part of a standard referral.

No member of the research team will be involved in screening identifiable personal information for potential study participants. Research team members will only be provided the information details of those potential participants who have been approached by a clinical team member and are agreeable to this information being passed on. This will occur at weekly meetings between members of the clinical and research team.

Potential caregiver participants will be identified through consenting patients included in the study and therefore will not be screened for.

To fulfill COREQ quality guidelines the number of patients screened by the clinical team will be monitored and reported on.

A27-4. Will researchers or individuals other than the direct care team have access to identifiable personal information of any potential participants?

○ Yes ◉ No

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

○ Yes ◉ No

A29. How and by whom will potential participants first be approached?

RECRUITMENT PROCESS: PATIENTS

Recruitment to the study will be over a six month period. All potential patient participants will be identified through the acute oncology and palliative care teams based at King's College Hospital. From the date of study commencement, a clinical member from each team (acute oncology and palliative care), will screen all new referrals received against the study inclusion/ exclusion criteria.

Eligible patients identified will first be approached by a clinical member of the acute oncology or palliative care team (dependent on which team the patient is under) within 2 weeks of their presentaion to the emergency department. Potential participants will not be approached whilst in the emergency department. When first approached, the clinical team member will introduce the study, explain that participation is entirely voluntary, and provide the patient with an information leaflet about the study. Patients will mostly be approached whilst in hospital (if admitted from the emergency department), however, if a potentially eligible patient has been discharged directly from the emergency department the clinical team member will telephone them at home regarding the study and their potential involvement.

Only patients who express an interest in the research and who are agreeable to meeting with a member of the research team will have their names passed on to the research team (such details will be shared weekly at a meeting between clinical and research team members). For these patients, Dr Lesley Henson (PhD clinical training fellow), or another member of the research team (including clinical research nurses), will follow-up the initial contact and be available to explain the study in detail, answer questions and address any concerns.

For patients who would like to participate, and after a minimum of 24 hours from first contact with a member of the research team, informed written consent to conduct an in-depth qualitative interview, and for a member of the research team to access the patients' healthcare records will be obtained by Dr Henson, or another member of the research team (including clinical research nurses). A minimum period of 24 hours between full explanation of the study and completion of the consent form will be advised for all participants in order to provide an opportunity for patients to reflect on the study and their involvement. If, after 24 hours, potential patient participants would like additional time to consider their involvement a future meeting time will be organised.

Some potential participants may feel that they do not require 24 hours to consider their involvement, and are comfortable to consent, or decline, earlier than this, for example some soon-to-be discharged patients may prefer to be interviewed before leaving hospital. In these situations the researcher will be guided by the patients' preferences for consenting.

RECRUITMENT PROCESS: CAREGIVERS

Eligible caregivers will be identified through patients recruited to the study, who will be asked if they have a caregiver. Eligible caregivers will therefore not be screened by the clinical palliative care or acute oncology teams. As caregivers may not be known to any particular healthcare team, they will first be approached by a member of the research team. For patients with a caregiver, consent will be sought from the patient for Dr Henson, or another member of the research team (including clinical research nurses) to contact the patients' caregiver regarding participation in the study. Only patients who provide informed consent for Dr Henson, or another member of the research team (including clinical research nurses) to approach their caregiver about the study will be contacted.

Where consent is provided, Dr Henson, or another member of the research team (including clinical research nurses) will contact the caregiver and introduce herself and the study. It will be explained that participation is entirely voluntary, and potential caregiver participants will be provided with an information leaflet about the study. After this initial contact potential caregiver participants will be given at least 24 hours to reflect on the study and consider their involvement. Dr Henson, or another member of the research team (including clinical research nurses) will then follow-up this initial contact and be available to answer questions, address any concerns, and ascertain the caregivers' interest in participating. If, after 24 hours, potential caregiver participants would like additional time to consider their involvement a future meeting time will be organised.

Some potential participants may feel that they do not require 24 hours to consider their involvement, and are comfortable to consent, or decline, earlier than this. In these situations the researcher will be guided by the caregivers' preferences for consenting.

A30-1. Will you obtain informed consent from or on behalf of research participants?

(●) Yes ( ) No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

All potential participants will have the study explained to them (initially by a clinical member of the palliative care or acute oncology team) and be provided with an information leaflet outlining the purpose of the study and including details of what participation would involve. An in-depth further explanation of the study will be given by Dr Lesley Henson (PhD clinical training fellow) or another member of the research team (including clinical research nurses).

Adequate time will be given for participants to read the study information leaflet (minimum of 24 hours) and ask Dr Henson, or another member of the research team (including clinical research nurses), any questions about the study and consider their involvement.

Once someone has decided that they would like to participate, they will be required to fully comprehend the risks, benefits and burden of their taking part, and give written informed consent to do so. Dr Henson, or another member of the research team (including clinical research nurses), who are trained and experienced in the consent process, will be responsible for obtaining consent from all participants. All members of the research team have completed Good Clinical Practice training at Kings College London.

Patients with advanced cancer can experience episodes of cognitive impairment and/ or sudden deteriorations in their overall health. Dr Henson is trained and experienced in assessing patients for cognitive impairment. This experience includes four years working as a palliative care physician. Dr Henson will assess the cognition of all patients prior to the consent process and again prior to the interview according to best practice guidelines (8). If a patient is found to have impaired cognition and/ or there is a sudden clinical deterioration, which impairs their ability to provide informed consent, the participant will be excluded from the study and the clinical team caring for the patient informed of the findings to ensure optimal medical management is administered. Any information that has been collected during the research process will be confidentially destroyed.

For any participant that decides to withdraw from the study no further data will be accessed or collected from the point of withdrawal onwards. Any prior data collected with consent will either be confidentially destroyed, or kept and included in the study analysis, depending on the preference of the participant. However, once data has been aggregated at the analysis stage of the study, withdrawal of individual patient information will no longer be possible. This will be explained during the consent process to all potential participants and is included in the participant information leaflets (version 1, 30.07.14).

REFERENCE
1) Matthews FE, Stephan BC, Khaw KT, et al. Full-scale scores of the Mini Mental State Examination can be generated from an abbreviated version. Journal of clinical epidemiology 2011; 64(9): 1005-13.

If you are not obtaining consent, please explain why not.

NA

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

(●) Yes ( ) No

A31. How long will you allow potential participants to decide whether or not to take part?

After initial contact has been made by a member of the research team, all potential study participants will be given at least 24 hours to reflect on and consider their involvement in the study. During this time they will have access to an information leaflet describing the study, its purpose, and what participation would involve.

Dr Lesley Henson (PhD clinical training fellow), or another member of the research team (including clinical research nurses), will follow-up this initial contact (after a minimum of 24 hours) and be available to answer questions and address any concerns. If, at this time, potential participants would like additional time to consider their involvement a future meeting time will organised.

Some potential participants may feel that they do not require 24 hours to consider their involvement, and are comfortable to consent, or decline, earlier than this, for example some soon-to-be discharged patients may prefer to be interviewed before leaving hospital. In these situations the researcher will be guided by the patients' preferences for consenting.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?*(e.g. translation, use of interpreters)*

For patients unable to adequately understand verbal or written English interpreters will be used.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

- ○ The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
- ◉ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
- ○ The participant would continue to be included in the study.
- ○ Not applicable – informed consent will not be sought from any participants in this research.
- ○ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

If you plan to retain and make further use of identifiable data/tissue following loss of capacity, you should inform participants about this when seeking their consent initially.

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)? *(Tick as appropriate)*

- ☑ Access to medical records by those outside the direct healthcare team
- ☐ Electronic transfer by magnetic or optical media, email or computer networks
- ☐ Sharing of personal data with other organisations
- ☐ Export of personal data outside the EEA
- ☑ Use of personal addresses, postcodes, faxes, emails or telephone numbers
- ☑ Publication of direct quotations from respondents
- ☐ Publication of data that might allow identification of individuals
- ☑ Use of audio/visual recording devices
- ☑ Storage of personal data on any of the following:
  - ☑ Manual files including X-rays
  - ☐ NHS computers
  - ☐ Home or other personal computers
  - ☐ University computers
  - ☐ Private company computers
  - ☐ Laptop computers

Further details:
All electronic data will be stored on an password protected, encrypted, external hard drive.

A38. How will you ensure the confidentiality of personal data? *Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

All participants will be assured of the procedures below that will be taken to ensure confidentiality:

All data collected will be anonymised according to departmental and college guidelines, (Department of Palliative Care, Policy & Rehabilitation, King's College London, (updated April 2010)).

Study participants will be assigned a unique identifier (code number) at the time of data collection. These codes will only be linked to person identifiable information in a research 'code book' which will be kept in a separate locked cabinet and away from any copies of the data itself.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

The Chief Investigator (Dr Barbara Daveson), the Doctoral student (Dr Lesley Henson), and her academic supervisors (Dr Wei Gao, Prof. Irene Higginson and the CI Dr Barbara Daveson) will have access to the participants' data during the study.

Storage and use of data after the end of the study

A43. How long will personal data be stored or accessed after the study has ended?

- (●) Less than 3 months
- ( ) 3 – 6 months
- ( ) 6 – 12 months
- ( ) 12 months – 3 years
- ( ) Over 3 years

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

(●) Yes ( ) No

If Yes, please give details. For monetary payments, indicate how much and on what basis this has been determined.
Study participants will not receive any payments or incentives for taking part, however, where reasonable travel expenses have been incured from participating in the project, for example travel costs to interview location, these will be reimbursed.

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

( ) Yes (●) No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

( ) Yes (●) No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

◉ Yes ○ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

A49-2. Will you seek permission from the research participants to inform their GP or other health/ care professional?

◉ Yes ○ No

It should be made clear in the participant's information sheet if the GP/health professional will be informed.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

◉ Yes ○ No

Please give details, or justify if not registering the research.
UKCRN Portfolio Database

Registration of research studies is encouraged wherever possible.
You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

- ☑ Peer reviewed scientific journals
- ☑ Internal report
- ☑ Conference presentation
- ☑ Publication on website
- ☑ Other publication
- ☐ Submission to regulatory authorities
- ☐ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- ☐ No plans to report or disseminate the results
- ☑ Other (please specify)

Dissemination of study findings to service-users and the general public through the Department of Palliative Care, Policy & Rehabilitation's 'Dissemination, Engagement and Empowerment Advisory Group' and the press department at King's College London.

A lay summary of the research findings will also be offered to all study participants.

A53. Will you inform participants of the results?

◉ Yes ○ No

Please give details of how you will inform participants or justify if not doing so.
After the study interview has been completed, participants will be asked if they would like to receive a copy of the findings. If participants would like this a copy will be sent to them when available.

Copies of the summary results and deatils of how to obtain further information will also be left with both the palliative care and acute onocology teams at Kings College Hospital.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed? *Tick as appropriate:*

- ☐ Independent external review
- ☐ Review within a company
- ☑ Review within a multi−centre research group
- ☑ Review within the Chief Investigator's institution or host organisation
- ☑ Review within the research team
- ☑ Review by educational supervisor
- ☐ Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
The study proposed forms part of Dr Lesley Henson's doctorate in palliative care and has been reviewed by her PhD educational supervisors. The study has also been internally peer reviewed within the Department of Palliative Care, Policy & Rehabilitation, King's College London.

In addition to the above departmental assessments, the project has been discussed by the Cicely Saunders Institute's International Scientific Expert Panel which includes world-leading palliative care experts such as Professor Eduardo Bruera and Baroness Ilora Finlay. The project has also been discussed at the 2014 BuildCARE All-assembly meeting which included palliative care researchers from London, Dublin and New York.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size:	80
Total international sample size (including UK):	80
Total in European Economic Area:	0

Further details:
The anticipated sample size for the research study proposed is up to 50 in-depth interviews with patients, and up to 30 in-depth interviews with caregivers.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

Qualitative studies typically involve inquiry and methodology that focus of producing detailed, rich information, and do not adhere to the predetermined statistically-based sample size calculations seen in quantitative research (1). Sample sizes therefore vary according to each study's overall aim, and decisions of the research team regarding depth versus breadth of information required (1).

For the present study data collection will continue until theoretical saturation is achieved, i.e. no new themes are emerging from new data collected, and all concepts are well-developed, and verified (2). Taking into consideration previous case-based qualitative research (3,4), a sample size of up to 50 patient interviews (plus review of their healthcare records), and up to 30 caregiver interviews, is anticipated to enable adequate in-depth exploration of the study phenomenon (5). An estimated 30% of potential patient participants will not have an identifiable caregiver to be recruited to the study and therefore additional interviews (up to 20) with just patients will be conducted. In addition to this prior research conducted by the Department of Palliative Care, Policy and Rehabilitation, has found that recruitment of caregivers, in particular patient-caregiver dyads, can be challenging. Multiple factors are likely to contribute to reduced caregiver recruitment, including, gate-keeping by patients who wish to reduce overall burden to their family member/ caregiver,(6) and many family members/ friends not identifying themselves as "caregivers", rather perceiving their role as "simply an extension of their relational role" (O'Connor, D.L., 2007, p168).(7) In order to help overcome some of these barriers, the definition of a "caregiver" will be clearly explained to all participants during recruitment, and the option of joint interviews will be offered to try and minimise the overall burden to study participants. This explanation has been developed with service-users representatives. The additional (up to 20) interviews with just patients also aims to minimise the impact from low caregiver recruitment on the study findings.

There will be an iterative approach towards data sampling (with concurrent data analysis informing ongoing data collection), that will determine when theoretical saturation is achieved, and therefore also the final sample size (2), however, in order to ensure successful devliery of the research project, a pragmatically derived maximum of 80 patient and caregiver interviews will be conducted due to time and resource limitations.

REFERENCES
1) Patton MQ, Patton MQ. Qualitative evaluation and research methods. 2nd ed. Newbury Park, Calif.: Sage Publications; 1990.
2) Given LM. The Sage encyclopedia of qualitative research methods. Los Angeles ; London: SAGE; 2008.
3) Tolson D, Fleming V, Schartau E. Coping with menstruation: understanding the needs of women with Parkinson's disease. J Adv Nurs 2002; 40(5): 513-21.
4) Baxter PE, Boblin S. Decision making by baccalaureate nursing students in the clinical setting. J Nurs Educ 2008; 47(8): 345-50.
5) Sandelowski M. Sample-Size in Qualitative Research. Res Nurs Health 1995; 18(2): 179-83.
6) Bausewein C, Calanzani N, Daveson BA, Simon ST, Ferreira PL, Higginson IJ, et al. 'Burden to others' as a public concern in advanced cancer: a comparative survey in seven European countries. BMC cancer. 2013;13:105. PubMed PMID: 23496878. Pubmed Central PMCID: 3637205.
7)O'Connor DL. Self-identifying as a caregiver: Exploring the positioning process. J Aging Stud. 2007 Apr;21(2):165-74. PubMed PMID: WOS:000246502600006. English.

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

Analysis will involve an interpretive layered approach (1) where each "case" (an instance of decision-making by a patient with advanced cancer, and/ or their caregiver, to attend the emergency department), will first be analysed individually using the multiple sources of data collected (patient interview, caregiver interview, and patient healthcare record).

Inductive content analysis of the interview transcripts and healthcare record data will identify concepts, and patterns and themes, emerging from each data source (1). Major concepts and themes from each data source will be combined and used to write a unique and holistic "case study", i.e. an account of that instance of decision-making by a patient with advanced cancer to attend the emergency department.

After each case is analysed individually, the main themes and sub-themes from all cases will be extracted and analysed. Links between themes and across cases (cross-case analysis) will be explored and allow for categories to be developed which will then be applied to the study's theoretical framework. Deviant cases will be explored to help understand the limits of any theories developed, as well as to assist with further theory development and hypothesis generation (2).

REFERENCES
1) Patton MQ, Patton MQ. Qualitative evaluation and research methods. 2nd ed. Newbury Park, Calif.: Sage Publications; 1990.
2) Denzin NK, Lincoln YS. The SAGE handbook of qualitative research. 3rd ed. ed. Thousand Oaks ; London: Sage Publications; 2005.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co−applicants, protocol co−authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title	Forename/Initials	Surname
	Dr	Lesley A	Henson
Post	Cicely Saunders International PhD Clinical Training Fellow		
Qualifications	MBBS, MRCP, BSc		
Employer	King's College London		
Work Address	King's College London, Cicely Saunders Institute		
	Bessemer Road		

	Denmark Hill, London
Post Code	SE5 9PJ
Telephone	02078485689
Fax	02078485517
Mobile	
Work Email	lesley.henson@kcl.ac.uk

Title	Forename/Initials	Surname
Dr	Wei	Gao

Post	Senior Lecturer
Qualifications	PhD, M.Med, B.Med, GCAP
Employer	King's College London
Work Address	King's College London, Cicely Saunders Institute
	Bessemer Road
	Denmark Hill, London
Post Code	SE5 9PJ
Telephone	02078485570
Fax	02078485517
Mobile	
Work Email	wei.gao@kcl.ac.uk

Title	Forename/Initials	Surname
Prof	Irene J	Higginson

Post	Professor and Head of Department of Palliative Care, Policy & Rehabilitation
Qualifications	PhD, FFPHM, BMBS, BMedSci
Employer	King's College London
Work Address	King's College London, Cicely Saunders Institute
	Bessemer Road
	Denmark Hill, London
Post Code	SE5 9PJ
Telephone	02078485516
Fax	02078485517
Mobile	
Work Email	irene.higginson@kcl.ac.uk

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- ○ NHS or HSC care organisation
- ◉ Academic
- ○ Pharmaceutical industry
- ○ Medical device industry
- ○ Local Authority
- ○ Other social care provider (including voluntary sector or private organisation)
- ○ Other

Commercial status: Non-Commercial

If Other, please specify:

Contact person

Name of organisation	King's College London
Given name	Keith
Family name	Brennan
Address	Room 1.8, Hodgkin Building, Guy's Campus
Town/city	London
Post code	SE1 4UL
Country	UNITED KINGDOM
Telephone	02078486960
Fax	02078486394
E-mail	keith.brennan@kcl.ac.uk

Is the sponsor based outside the UK?
○ Yes ◉ No

Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.

A65. Has external funding for the research been secured?

☑ Funding secured from one or more funders
☐ External funding application to one or more funders in progress
☐ No application for external funding will be made

What type of research project is this?

○ Standalone project
◉ Project that is part of a programme grant
○ Project that is part of a Centre grant
○ Project that is part of a fellowship/ personal award/ research training award
○ Other

Other – please state:
Part of the "International Access, Rights and Empowerment Study: an international mixed methods study to compare palliative care experiences among older people affected by cancer and non cancer conditions" (IRAS project ID: 97065, REC reference: 12/LO/0044)

Please give details of funding applications.

Organisation	Cicely Saunders International
Address	Cicely Saunders Institute Bessemer Road, Denmark Hill London
Post Code	SE5 9PJ
Telephone	02078485580
Fax	
Mobile	

Email brenda.ferns@cicelysaundersinternational.org

Funding Application Status: (•) Secured ( ) In progress

Amount: £2,443,112.00

Duration

Years: 4

Months: 0

If applicable, please specify the programme/ funding stream:

What is the funding stream/ programme for this research project?

This project forms part of a larger programme of palliative care research, project BuildCARE, for which funding has been secured.

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

( ) Yes (•) No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

	Title	Forename/Initials	Surname
	Dr	Zoe	Harris
Organisation	King's College Hospital NHS Foundation Trust		
Address	1st Floor		
	161 Denmark Hill		
	London		
Post Code	SE5 8EF		
Work Email	z.harris@nhs.net		
Telephone	02032993841		
Fax	02032995515		
Mobile			

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A68-2. Select Comprehensive Local Research Network for this NHS organisation:

To support communication between the REC and R&D contacts for this study, please select the Comprehensive Local Research Network (CLRN) for this NHS organisation. This CLRN will be the Lead CLRN for your study.

London (South)

For information about support and advice available through the Lead CLRN and the CLRNs for participating sites see http://www.crncc.nihr.ac.uk/about_us/processes/csp. A map showing the CLRNs is available at http://www.crncc.nihr.ac.uk/about_us/ccrn.

A69-1. How long do you expect the study to last in the UK?

Planned start date: 29/09/2014
Planned end date: 03/04/2015
Total duration:
Years: 0 Months: 6 Days: 5

A71-2. Where will the research take place? *(Tick as appropriate)*

- [x] England
- [ ] Scotland
- [ ] Wales
- [ ] Northern Ireland
- [ ] Other countries in European Economic Area

Total UK sites in study 1

Does this trial involve countries outside the EU?
○ Yes ◉ No

A72. What host organisations (NHS or other) in the UK will be responsible for the research sites? *Please indicate the type of organisation by ticking the box and give approximate numbers of planned research sites:*

[x] NHS organisations in England	1
[ ] NHS organisations in Wales	
[ ] NHS organisations in Scotland	
[ ] HSC organisations in Northern Ireland	
[ ] GP practices in England	
[ ] GP practices in Wales	
[ ] GP practices in Scotland	
[ ] GP practices in Northern Ireland	
[ ] Social care organisations	
[ ] Phase 1 trial units	
[ ] Prison establishments	
[ ] Probation areas	
[ ] Independent hospitals	
[ ] Educational establishments	
[ ] Independent research units	
[ ] Other (give details)	
Total UK sites in study:	1

A76. Insurance/ indemnity to meet potential legal liabilities

***Note:* in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland**

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes.

Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

☑ NHS indemnity scheme will apply (NHS sponsors only)

☑ Other insurance or indemnity arrangements will apply (give details below)

King's College London Standard Indemnity.

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (protocol authors with NHS contracts only)

☑ Other insurance or indemnity arrangements will apply (give details below)

King's College London Standard Indemnity.

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

☑ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)

☐ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the Institution row and insert the research site (e.g. GP practice) in the Department row.*

Investigator identifier	Research site		Investigator Name	
IN1 ☐	◉ NHS site ○ Non-NHS site		Forename	Rachel
			Middle name	
			Family name	Burman
	Country: England		Email	rachel.burman@nhs.net
			Qualification (MD...)	MBBS, Consultant in Palliative Care and Honorary Senior Lecturer
			Country	UNITED KINGDOM
	Organisation name	KING'S COLLEGE HOSPITAL NHS FOUNDATION TRUST		
	Address	DENMARK HILL		
		LONDON GREATER LONDON		
	Post Code	SE5 9RS		

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.

3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.

4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.

5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.

6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.

7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.

8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.

9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:

    - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
    - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
    - May be sent by email to REC members.

10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.

11. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication *(Not applicable for R&D Forms)*

NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

◯ Chief Investigator

◯ Sponsor

- ○ Study co-ordinator
- ◉ Student
- ○ Other – please give details
- ○ None

Access to application for training purposes *(Not applicable for R&D Forms)*

Optional – please tick as appropriate:

☑ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Dr Barbara Daveson on 05/08/2014 09:33.

Job Title/Post:	Cicely Saunders International Lecturer in Health Services Research
Organisation:	King's College London
Email:	bdaveson@gmail.com
Signature:	.....
Print Name:	Dr Barbara A Daveson
Date:	*(dd/mm/yyyy)*

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co−sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.
2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.
3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.
4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.
5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.
6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.
7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

This section was signed electronically by Mr Keith Brennan on 05/08/2014 09:08.

Job Title/Post:	Director of Research Management
Organisation:	King's College London
Email:	keith.brennan@kcl.ac.uk

D3. Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

2. I undertake to fulfil the responsibilities of the supervisor for this study as set out in the Research Governance Framework for Health and Social Care.

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Academic supervisor 1

This section was signed electronically by Professor Irene Higginson on 05/08/2014 10:22.

Job Title/Post:	Professor of Palliative Care
Organisation:	King's College London
Email:	irene.higginson@kcl.ac.uk

Academic supervisor 2

This section was signed electronically by Dr Wei Gao on 04/08/2014 18:48.

Job Title/Post:	senior lecturer
Organisation:	King's COllege London
Email:	wei.gao@kcl.ac.uk

Academic supervisor 3

This section was signed electronically by Dr Barbara Daveson on 05/08/2014 09:34.

Job Title/Post:	Cicely Saunders International Lecturer in Health Services Research
Organisation:	King's College London
Email:	bdaveson@gmail.com

NHS
Health Research Authority

NRES Committee South Central - Berkshire
Bristol REC Centre
Whitefriars
Level 3, Block B
Lewins Mead
Bristol
BS1 2NT

Telephone: 0117 3421389

28 August 2014

Dr Barbara A Daveson
King's College London, Cicely Saunders Institute
Department of Palliative Care, Policy & Rehabilitation
Bessemer Road
SE5 9PJ

Dear Dr Daveson,

Study title:	**How do patients with advanced cancer decide to attend the emergency department, and what influences their decision-making at this time? A qualitative case study**
REC reference:	**14/SC/1207**
IRAS project ID:	**157391**

The Research Ethics Committee reviewed the above application at the meeting held on 19 August 2014. Thank you and Dr Lesley Henson for attending to discuss the application.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the REC Manager Ms Rae Granville, nrescommittee.southcentral-berkshire@nhs.net.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below. .

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

1. Advisory point: Please give the patient information sheet to the PPI group to see if it can be improved. Any changes should be submitted as a minor amendment.
2. Please add a short statement to the PIS: 'Patients who choose to travel to the Macmillan Centre or other facilities to participate in interviews will have travel

expenses reimbursed'.

3. Please add a sentence to the GP letter informing them that you may need to access patient records. Viz. 'It might be helpful for me to gain access to participants' community records; I would be grateful if you could permit this if necessary'.
4. Please add a sentence to the patient information sheet informing them that their GP will be contacted. Viz. 'Your GP will be informed of your participation in this study'.

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on question 2 of the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Summary of discussion at the meeting

Care and protection of research participants; respect for potential and enrolled participants' welfare and dignity

The Committee requested clarification of arrangements in place for reimbursement of travel expenses. Dr Hensen replied that the majority of patients would be interviewed at the hospital. Some would be interviewed at their home once discharged. She added that a few may travel to the local Macmillan Centre for the interview and their travel expenses would be reimbursed but the majority would be interviewed at the hospital. The Committee was satisfied with this response and requested that Dr Hensen amend the patient information sheet to take this into account.

The Committee pointed out that there was a potential four week window between taking consent and the interview. It questioned what process was in place to assess the status of a participant; if they had deteriorated or died in the interim. Dr Hensen answered that the patient undergoes screening every week by the oncology team and would be informed if their health had deteriorated. She explained that she had added an extra two weeks in case the patient was ill. For those patients who have been discharged, she would contact the oncology team or GP to check their status before calling. The Committee was content with this answer.

The Committee was concerned about the duration of the interview. It felt that one hour could be too burdensome for this patient group. Dr Hensen replied that the length of the interview was determined by similar studies completed in the department. Normally these interviews did not last the full hour, but she could shorten or split the interview if the patient was fatigued. She explained that the interview was patient led and if a patient was fatigued the more pertinent questions were asked first. Dr Hensen added that a lot of data could be captured from a single response. The Committee was satisfied with this answer.

Informed consent process and the adequacy and completeness of participant information

The Committee pointed out that the patient information sheet was not in layman's language in some places. It asked how Dr Hensen intended to approach patients and explain the study. Dr Hensen replied that the oncology and palliative care team would approach the patient and give a brief explanation of the study before handing them a patient information sheet. When the patient decided to become involved their details would be passed to the research team who would go through the patient information sheet in more detail with the patient. The Committee was content with this answer.

The Committee noted the patient information sheet stated that all cancer patients would be able to take part in the study but this was untrue as there was an exclusion criterion relating to patients in hospices and nursing homes. It requested that this be made clear in the patient information sheet. Dr Hensen agreed.

The Committee requested that Dr Hensen include the fact that the patients GP would be contacted in the patient information sheet. Dr Hensen agreed.

Dr Hensen informed the Committee that there was a large PPI group at the hospital and she could ask them to review the patient information sheet to improve it. The Committee was satisfied and would be content for these improvements to be submitted as a minor amendment.

Suitability of supporting information

The Committee observed that Dr Hensen would be accessing community GP records. It requested that this fact be added to the GP letter. Dr Hensen agreed.

Other general comments

Dr Hensen explained that there were inconsistencies in the documentation and clarified that 80 interviews would be taking place of which 30 would be carers and 50 patients.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
GP/consultant information sheets or letters	1	30 July 2014
Interview schedules or topic guides for participants	1	30 July 2014
Interview schedules or topic guides for participants	1	30 July 2014
Other [IJH CV (summary CV for supervisor)]	1	05 June 2014
Other [GW CV (summary CV for supervisor)]	1	05 June 2014
Participant consent form	1	30 July 2014
Participant consent form	1	30 July 2014
Participant information sheet (PIS) [Patient Information Leaflet]	1	30 July 2014
Participant information sheet (PIS) [Caregiver Information Leaflet]	1	30 July 2014
REC Application Form [REC_Form_05082014]		05 August 2014
Research protocol or project proposal	1	30 July 2014
Summary CV for Chief Investigator (CI) [BD CV_short]	1	19 July 2014
Summary CV for student	1	05 June 2014
Summary CV for supervisor (student research)	1	19 July 2014

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

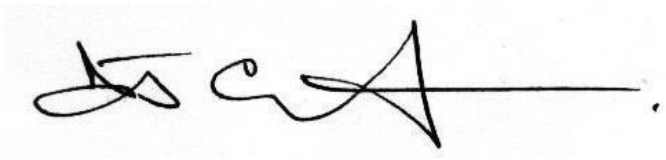
HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

14/SC/1207	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely,



Mr David Carpenter
Chair

E-mail: nrescommittee.southcentral-berkshire@nhs.net

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

After ethical review – guidance for researchers

Copy to: *Mr Keith Brennan*
Dr Zoe Harris, King's College Hospital NHS Foundation Trust

NRES Committee South Central - Berkshire

Attendance at Committee meeting on 19 August 2014

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mr David Carpenter	Social Scientist	Yes	
Dr Mike Emanuel	Pharmaceutical Consultant	Yes	
Mrs Liz Hunter	Retired Midwife and Clinical Governance Manager	Yes	
Dr Vandana Luthra	R&D Research Co-ordinator	Yes	
Mr Daniel Charles Mace	Retired Corporate Lawyer	Yes	
Mr Richard Merewood	Director	Yes	
Mr Neil Thomas O'Kane	Aviation Safety Consultant	Yes	
Dr Joanne Philpot	Consultant Paediatrician	Yes	
Dr Mike Proven	Co-ordinator for QA in Research	Yes	
Ms Ann Quinn	Head of the School of Health and Social Care	Yes	
Mr Donald Scott-Collett	Lead Pharmacist for Elderly Care, Neuro-rehabilitation, Dermatology and Clinical Governance	No	
Dr John Andrew Sutton	Medical Director	Yes	
Ms Susan Tonks	Senior Research Support Associate	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Cathy Chesham	Deputy Regional Manager
Ms Rae Granville	REC Manager

NHS
Health Research Authority

NRES Committee South Central - Berkshire
Bristol REC Centre
Whitefriars
Level 3, Block B
Lewins Mead
Bristol
BS1 2NT

Telephone: 0117 342 1333
Fax:0117 342 0445

15 September 2014
Amended and Reissued 15 October 2014

Dr Barbara A Daveson
King's College London, Cicely Saunders Institute
Department of Palliative Care, Policy & Rehabilitation
Bessemer Road
SE5 9PJ

Dear Dr Daveson

Study title: **How do patients with advanced cancer decide to attend the emergency department, and what influences their decision-making at this time? A qualitative case study**
REC reference: **14/SC/1207**
IRAS project ID: **157391**

Thank you for your letter of 15th September 2014. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 28 August 2014

Documents received

The documents received were as follows:

Document	*Version*	*Date*
GP/consultant information sheets or letters	2	01 September 2014
Other [REC correspondence]	1	15 September 2014
Participant information sheet (PIS) [Patient Information Leaflet]	2	01 September 2014
Participant information sheet (PIS) [Caregiver Information Leaflet]	2	01 September 2014

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
GP/consultant information sheets or letters	2	01 September 2014
Interview schedules or topic guides for participants	1	30 July 2014

Interview schedules or topic guides for participants	1	30 July 2014
IRAS Checklist XML [Checklist_15092014]		15 September 2014
IRAS Checklist XML [Checklist_09092014]		09 September 2014
Other [REC correspondence]	1	15 September 2014
Other [GW CV (summary CV for supervisor)]	1	05 June 2014
Other [IJH CV (summary CV for supervisor)]	1	05 June 2014
Participant consent form [Patient]	1	30 July 2014
Participant consent form [Caregiver]	1	30 July 2014
Participant information sheet (PIS) [Patient Information Leaflet]	2	01 September 2014
Participant information sheet (PIS) [Caregiver Information Leaflet]	2	01 September 2014
REC Application Form [REC_Form_05082014]		05 August 2014
Research protocol or project proposal	1	30 July 2014
Summary CV for Chief Investigator (CI) [BD CV_short]	1	19 July 2014
Summary CV for student	1	05 June 2014
Summary CV for supervisor (student research)	1	19 July 2014

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

14/SC/1207	**Please quote this number on all correspondence**

Yours sincerely

T. Fairman

Mr Thomas Fairman
REC Manager

E-mail: nrescommittee.southcentral-berkshire@nhs.net

Copy to: *Mr Keith Brennan*
Dr Zoe Harris, King's College Hospital NHS Foundation Trust

Appendix E - Qualitative Interview Study Distress Protocol

Distress Protocol

The proposed study is expected to have minimal risk for participants. Nonetheless, participants (advanced cancer patients and their caregivers) may find being interviewed distressing, particularly when discussing problems they have experienced during the course of their illness, and/ or the illness of their loved one. Interviews may, for example, uncover physical complaints, psycho-social concerns, and/ or other problems being experienced by the patient and/ or their caregiver.

In order to help prevent undue concerns, the following steps will be taken for all interviews:

1. At the beginning of each interview, it will be emphasised that:
    - Participation is entirely voluntary and that the participant can withdraw from the study at any time.
    - Participants do not have to answer any question(s) that they do not feel comfortable with.
    - Participants can stop the interview at any time, and for any reason.
2. At the end of each interview, time will be set aside to ensure that all respondents are comfortable with the process of the interview.
3. All participants will be provided with the contact details for the Macmillan Information & Support Centre, based at the Cicely Saunders Institute, King's College Hospital. The purpose of the Macmillan centre is to provide information, support and a welcoming relaxed environment for patients, carers or family and friends of people with cancer or other long term conditions.

In the event of the interview being terminated earlier and/ or resulting in participant distress, the following additional steps will also be taken:

1. The research team member will encourage the participant to seek help from their GP, especially if the issue raised is one regarding the participants own physical or mental wellbeing.

2. For an interview terminated by the participant:

    - If there is a family member or friend present, the researcher will offer any required support and ensure that the participant is comfortable before leaving.

    - If no-one else is present, participants will be encouraged by the research team member to contact a friend or family member. The researcher will remain with the participant (if they are agreeable to this) until this additional support is available.

    - Should the participant be unable or unwilling to identify someone to contact, the researcher will offer any required support and ensure that the participant is comfortable before leaving. The research team member will then make contact with the participant, within 24 hours, to further ensure that the participant is not unduly distressed, and ascertain whether any further support is required.

3. Should a researcher have serious concerns regarding the physical and/ or mental wellbeing of a participant, this will be discussed as a matter of urgency with one of the research study supervisors and appropriate action will then be taken.

What will happen to the results of the research study?

We have planned for the results to be made available to other healthcare professionals through a series of articles published in scientific journals. You will not be identified in any report or publication. If you would like a copy of the report or article please let us know.

What do I do now?

You have been given this leaflet to read and think about whether you wish to take part or not. Consider all the information, perhaps talk it over with your family, and note down any further questions you may have. If you do want to take part, a member of the research team will arrange a time to come back and talk through the study with you and ask you to sign the consent form. If you would rather not be involved, we will make a note of this, so you are not asked again.

Lastly….

Thank you for taking time to consider this study. We hope that this study will make a considerable difference to the way symptoms and other urgent situations are managed for people living with advanced cancer.

Please, if you have any further questions or concerns contact:

Dr Lesley Henson
Cicely Saunders International PhD Clinical Training Fellow,
King's College London, Cicely Saunders Institute,
Bessemer Road, LONDON, SE5 9PJ
Tel: +44 207 848 5689 / 5516 **Email:** lesley.henson@kcl.ac.uk

King's College London University of London | King's College Hospital NHS Foundation Trust | BuildCARE

HOW DO PATIENTS WITH ADVANCED CANCER DECIDE TO ATTEND THE EMERGENCY DEPARTMENT, AND WHAT INFLUENCES THEIR DECISION-MAKING AT THIS TIME? A QUALITATIVE CASE STUDY

We would like to invite you to take part in our research study. Before you decide whether you would like to be involved, we would like to explain why the research is being done, and what participation would mean for you.

Purpose of study

Many people living with advanced cancer experience situations that require urgent care and attention. Sometimes these situations can be managed at home. At other times they may require people to visit the emergency department. Occasionally, situations that could be better managed at home result in people visiting the emergency department.

With this study, we are aiming to understand how and why people living with advanced cancer decide to attend the emergency department. We feel that the best way to improve our understanding is to speak to people like you who have recently attended the emergency department so we can learn from their experiences.

What will happen to me if I take part?

We would like to conduct an interview with you which will be audio recorded. During the interview we will ask you some questions about the most recent time that you visited the emergency

department. Don't worry, there are no right or wrong answers - all the questions are about you and your experience. We may also want to interview a family member or close friend of yours and will ask you to identify someone that we could approach. If you don't want us to approach any of your family members or friends that is okay, just tell us and we won't.

We understand that your time is valuable. If you agree to be interviewed this will take approximately one hour. You do not have to answer any questions you do not want to, and you can stop the interview at any time. If at any time you feel unable to continue with the study we will not ask you any further questions.

You will **NOT** be required to fill in any surveys or questionnaires.

We would also like to look at some of your healthcare records and will ask for your consent so we can access these documents.

Although we cannot pay you for your participation we will reimburse any reasonable expenses that you may incur from taking part in the study, for example, travel costs to attend for the interview.

Do I have to take part?

No. It is up to you to decide if you want to join the study. If you decide to take part in the study this will **NOT** affect any aspect of care or treatment that you receive.

If you agree to take part, we will ask you to sign a consent form. You are free to withdraw from the study at any time and without giving a reason. If you decide to withdraw, no further data will be collected or research procedures carried out. If some data has already been collected you can choose whether we destroy or keep this, but only up to the point of data analysis. Data analysis occurs 4-12 weeks after the interview and at this point your data will be merged with other participants making retrieval and removal of your information not possible after this time.

What are the possible benefits of taking part?

We cannot promise that the study will help you, however, the information we get from this study will help us understand more about why people living with cancer go to the emergency department and how we may improve the healthcare services available for people living with cancer.

Will my taking part in the study be kept confidential?

Any information you give to us will be kept confidential and secure by the research team. If however, you tell us something that makes us concerned about your safety, or the safety of others, we may have to break confidentiality and inform your GP or another professional regarding this.

We would like to write to your GP to inform them of your participation in the study and will ask your permission to do this.

What if there is a problem?

If you have concerns about any aspect of this study you should speak to a member of the research team or contact the patient advice and liaison service (PALS) at King's College Hospital on **020 3299 3601.**

What will happen to the results of the research study?
We have planned for the results to be made available to other healthcare professionals through a series of articles published in scientific journals. You will not be identified in any report or publication. If you would like a copy of the report or article please let us know.

What do I do now?
You have been given this leaflet to read and think about whether you wish to take part or not. Consider all the information, perhaps talk it over with your family, and note down any further questions you may have. If you do want to take part, a member of the research team will arrange a time to come back and talk through the study with you. If you would rather not be involved, we will make a note of this, so you are not asked again.

Lastly….
Thank you for taking time to consider this study. We hope that this study will make a considerable difference to the way symptoms and other urgent situations are managed for people living with advanced cancer.

Please, if you have any further questions contact:
Dr Lesley Henson
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King's College Hospital NHS
NHS Foundation Trust

BuildCARE

HOW DO PATIENTS WITH ADVANCED CANCER DECIDE TO ATTEND THE EMERGENCY DEPARTMENT, AND WHAT INFLUENCES THEIR DECISION-MAKING AT THIS TIME? A QUALITATIVE CASE STUDY

We would like to invite you to take part in our research study. Before you decide whether you would like to be involved, we would like to explain why the research is being done, and what participation would mean for you. One of our team will go through this information sheet with you and answer any questions that you have.

Purpose of study

Many people living with advanced cancer experience situations that require urgent care and attention. Sometimes these situations can be managed at home. At other times they may require people to visit the emergency department. Occasionally, situations that could be better managed at home result in people visiting the emergency department.

With this study, we are aiming to understand how, and why, people living with advanced cancer decide to attend the emergency department.

We also want to explore these decisions with their family and friends.

Why have I been invited?
Your family member or friend has been asked to take part in our study. They have told us that you help care for them, and might also be able to take part.

Do I have to take part?
No. It is up to you to decide if you want to join the study. If you decide to take part in the study this will **NOT** affect any aspect of care or treatment that you or your family member/ friend receive.

If you agree to take part, we will ask you to sign a consent form. You are free to withdraw from the study at any time and without giving a reason. If you decide to withdraw, no further data will be collected or research procedures carried out. If some data has already been collected you can choose whether we destroy or keep this, but only up to the point of data analysis. Data analysis occurs 4-12 weeks after the interview and at this point your data will be merged with other participants making retrieval and removal of your information not possible after this time.

What will happen to me if I take part?
We would like to conduct an interview with you which will be audio recorded. During the interview we will ask you some questions about the most recent time that your family member/ friend visited the emergency department. Don't worry, there are no right or wrong answers - all the questions are about you and your experience.

We understand that your time is valuable. If you agree to be interviewed this will take approximately one hour. You do not have to answer any questions you do not want to, and you can stop the interview at any time. If at any time you feel unable to continue with the study we will not ask you any further questions.

You will **NOT** be required to fill in any surveys or questionnaires.

Although we cannot pay you for your participation we will reimburse any reasonable expenses that you may incur from taking part in the study, for example, travel costs to attend for the interview.

What are the possible benefits of taking part?
We cannot promise that the study will help you or your friend/ family member. The information we get from this study will help us understand how people make decisions about going to the emergency department and will help us improve healthcare services for people living with advanced cancer.

Will my taking part in the study be kept confidential?
Yes. Any information you give to us will be kept confidential and secure by the research team. If however you tell us anything that makes us concerned about your safety, or the safety of others, we may have to break confidentiality and inform your family doctor or other professional regarding this.

What if there is a problem?
If you have concerns about any aspect of this study you should speak to a member of the research team or contact the patient advice and liaison service (PALS) at King's College Hospital on **020 3299 3601.**

Appendix G - Qualitative Interview Study Patient and Caregiver Consent Forms

King's College Hospital NHS
NHS Foundation Trust

Centre Number: King's College Hospital
Patient Identification number for this study: ED___
Study Number: UKCRN ID 17701, IRAS ID 157391

PATIENT CONSENT FORM

TITLE OF PROJECT: HOW DO PATIENTS WITH ADVANCED CANCER DECIDE TO ATTEND THE EMERGENCY DEPARTMENT, AND WHAT INFLUENCES THEIR DECISION-MAKING AT THIS TIME? A QUALITATIVE CASE STUDY

Name of Researcher: **Lesley A Henson** Please initial all boxes

1. I confirm that I have read and understand the information sheet dated 01.09.2014 (version 2) for the above titled study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary, and I am free to withdraw at any time without giving any reason, and without my medical care or legal rights being affected. ☐
3. I agree to take part in a face-to-face interview with a researcher and for this to be recorded electronically. ☐
4. I agree to sections of my medical records (including my hospital records, general practitioners records and/ or community palliative care records) being viewed by members of the research team. ☐
5. I agree that my details will be kept on an anonymised database and that the electronic recording of my interview will be kept for seven years. ☐
6. I agree to the information provided in the interviews to be anonymised and used for teaching purposes. ☐
7. I agree to my GP being informed of my participation in the study. ☐
8. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Person Taking Consent	Date	Signature

Version 1 Patient Consent Form 30.07.2014

Centre Number:

Patient Identification number for this study:

Study Number:

CAREGIVER CONSENT FORM

TITLE OF PROJECT: HOW DO PATIENTS WITH ADVANCED CANCER DECIDE TO ATTEND THE EMERGENCY DEPARTMENT, AND WHAT INFLUENCES THEIR DECISION-MAKING AT THIS TIME? A QUALITATIVE CASE STUDY

Name of Researcher: **Lesley A Henson** Please initial all boxes

1. I confirm that I have read and understand the information sheet dated **01.09.2014** (version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary, and I am free to withdraw at any time without giving any reason, and without mine or my family member/ friend's medical care or legal rights being affected. ☐
3. I agree to take part in a face-to-face interview with a researcher and for this to be recorded electronically. ☐
4. I agree that my details will be kept on an anonymised database and that the electronic recording of my interview will be kept for seven years. ☐
5. I agree to the information provided in the interviews to be anonymised and used for teaching purposes. ☐
6. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Person Taking Consent	Date	Signature

Appendix H - Qualitative Interview Study Patient and Caregiver Interview Topic Guides

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Topic Guide: Patient

How do patients with advanced cancer decide to attend the emergency department, and what influences their decision-making at this time? A qualitative case study

Aim: To investigate the processes by which advanced cancer patients, and their caregivers, decide to attend the emergency department, and; to explore advanced cancer patients', and their caregivers', preferences for an urgent care service.

Introduction:

- Introduce researcher and study purpose.
- Thank participant for taking part.
- Explain that this is an opportunity for the participant to tell the researcher, in their own words, why they decided to attend the ED and how the decision to go to the ED came about.

Administrative Tasks:

- Describe the interview process, including the following:
    - The interview will be audio recorded.
    - All information from the interview will remain confidential unless there are concerns regarding the safety of the participant, others, and/ or information is disclosed that is required to be reported by law.
    - Expected interview duration is approximately 60 minutes.
    - The participant can stop the interview at any time and/ or decline to answer any questions asked.
    - There are no right or wrong answers.

- Encourage the participant to speak freely throughout the interview. Reassure participant that any names or identifying information disclosed will be removed when the interview is transcribed.

- Make sure the participant understands that the interview is regarding their most recent ED visit: probe participant for the date/ time of patient's most recent ED visit. Check that this is consistent with study records.

Check Written Consent Form

---------- **START RECORDING** ----------

Icebreaker:

	Examples
1. General question aiming to put participant at ease	**"Tell me a little bit about yourself, and who the key people are in your life?"** ***OR*** **"How did you come to be in your current situation?"**

Cancer Background

Topic Areas to be Covered	**Examples**
1. Explore background to cancer diagnosis • What type of cancer? • When were they diagnosed? • What is the current situation regarding their disease status?	**"Can you tell me about your diagnosis of cancer?"** **OR** **"Can you tell me about when you were first diagnosed with cancer and what has happened since then"** **"How is your health at the moment?"**

ED Attendance:

Topic Areas to be Covered	Examples
1. Explore the events surrounding the patient's ED attendance • Where was the patient? • Were they alone? • How did they get to the ED? • Did they go to the ED alone or with someone else?	**"I'm interested in knowing more about the time that you came to the ED. What can you tell me about that day?"** ***OR*** **"Talk me through what happened that day."**

Explore Decision Making:

Topic Areas to be Covered	Example Questions
1. Explore the decision to go to the ED • Who made the decision to go to the ED? • Who else was involved in making the decision? • Were there differences in opinions? • How long did it take to make the decision?	**"Explain to me how the decision to attend the ED came about?"** **"Talk me through your thoughts during this time."**
2. Explore influencing factors in decision making • What were the factors? • What made them important? • If not mentioned by participant, ask specifically whether any of the following factors influenced decision making: a. **Symptoms** experienced by the patient; b. **Access** to healthcare services (both physical in terms of location of patient to the service and non-physical in terms of the availability of such	**"What things did you weigh-up when deciding whether or not to go to the ED?"** **"You've told me about these important factors that influenced your decision-making [list factors mentioned]. Explain to me why they were important and how they influenced your decision?"**

service);

c. **Religion**;
d. Previous **end of life discussions or advance care planning**;
e. **Previous advice** or guidance provided about healthcare services and utilisation;
f. **The set-up at home** (e.g. living alone? Married? Children in the house); and
g. **Previous patterns of consulting behaviour** and **experiences of healthcare services** (including both the ED and elsewhere)

3. Explore hierarchy and relationship between factors mentioned • Was there one factor that was the most important? • Were there factors that were not so important? • Were they related?	**"Were any of these factors you've mentioned more important than others? In what way?"** **"Do you think any of these factors were related to each other? In what way are they related? Or are they separate things that you considered individually?"**

<u>Experience at ED and reflecting on decision:</u>

Topic Areas to be Covered	**Examples**
1. Explore ED experience further	**"Tell me a bit about what happened when you arrived at the ED?"**

2. Explore previous healthcare utilisation behaviour • Have there been similar situations in the past? • Did they act the same or differently?	**"Have you been that unwell before?"**
3. Ask participant to reflect on decision	**"Looking back now, what are your reflections on the experience and decision that was made?"** ***OR*** **"If the same situation arose again, would you do anything differently? What would you do differently?"**
4. Explore preferences for acute care services • Would they prefer care at home or in hospital? • Why?	**"If you needed urgent care again, can you describe to me what you would consider an ideal service?"**

Concluding Interview

1. Remind participant about the study purpose	**"The purpose of this study is to try and understand how people with cancer, and their family or friends decide to go to the ED. Are there any areas that we haven't talked about that you feel would be important to discuss?"**
2. Ask for any final thoughts or comments	**"Do you have any questions, final thoughts or comments?"**

---------- STOP RECORDING ----------

---------- COMPLETE PARTICIPANT DEMOGRAPHICS FORM ----------

Final Tasks:

- Check participant is okay with the interview process and enquire if they would like any additional support at this time. If participant shows any signs of distress refer to Distress Protocol for further action.
- Leave details of the Macmillan Information & Support Centre, based at the Cicely Saunders Institute, King's College Hospital.
- Ask patient if they would like a copy of the study findings sent to them.
- Thank participant.

Topic Guide: Caregiver

How do patients with advanced cancer decide to attend the emergency department, and what influences their decision-making at this time? A qualitative case study

Aim: To investigate the processes by which advanced cancer patients, and their caregivers, decide to attend the emergency department, and; to explore advanced cancer patients', and their caregivers', preferences for an urgent care service.

Introduction:

- Introduce researcher and study purpose.
- Thank participant for taking part.
- Explain that this is an opportunity for the participant to tell the researcher, in their own words, what happened when their family member/ close friend attended the ED, and how the decision to go to the ED came about.

Administrative Tasks:

- Describe the interview process, including the following:
    - The interview will be audio recorded.
    - All information from the interview will remain confidential unless there are concerns regarding the safety of the participant, others, and/ or information is disclosed that is required to be reported by law.
    - Expected interview duration is approximately 60 minutes.
    - The participant can stop the interview at any time and/ or decline to answer any questions asked.
    - There are no right or wrong answers.

- Encourage the participant to speak freely throughout the interview. Reassure participant that any names or identifying information disclosed will be removed when the interview is transcribed.

- Make sure the participant understands that the interview is regarding the patient's most recent ED visit: probe participant for the date/ time of patient's most recent ED visit. Check that this is consistent with study records.
  - *If **NOT** consistent, then ensure that the participant is unaware of any more recent ED visits, but, do not disclose any details of the most recent ED visit. (**"As far as you know, that was the last time that [inserts patient's name] visited the ED?").** Document the date and time of this ED visit and proceed to interview regarding this episode.*

Check Written Consent Form

---------- **START RECORDING** ----------

Icebreaker:

	Examples
1. General question aiming to put participant at ease	**"Tell me a little bit about yourself and who the key people are in your life"**

Explore Participant's Relationship to Patient:

Topic Areas to be Covered	**Examples**
1. Clarify and explore the participant's relationship to the patient	**"How do you know [insert patient's name]?"**
• How long have they known each other?	
• Are they family members or friends?	**"Tell me about your relationship with [insert patient's name]"**
• Do they live together?	

2. Explore the participants role as caregiver • How long has the participant been involved in the patient's care? • Are they the only caregiver? • Do others help with caring? Who?	**"How are you involved with [insert patient's name] care?"** **"Describe to me what a typical day caring for [insert patient's name] consists of?"**
3. Explore any particular challenges experienced with being a caregiver	**"How do you find caring for [insert patient's name]?"** ***OR*** **"What do you find most challenging about being a caregiver?"**

ED Attendance:

Topic Areas to be Covered	Examples
1. Explore the events surrounding the patient's ED attendance • Where was the patient? • Where was the participant? • Did they participant go to the ED with the patient?	**"I'm interested in knowing more about the time that [insert patient name] came to the ED.** **What can you tell me about that day?** ***OR*** **Talk me through what happened that day?"**

Explore Decision Making:

Topic Areas to be Covered	Examples
1. Explore the decision to go to the ED • Who made the decision to go to the ED? • Who else was involved in making the decision?	**"Explain to me how it was decided that [insert patient's name] should go to the ED."**

- Were there differences in opinions?
- How long did it take to make the decision?

2. Explore influencing factors in decision making
   - What were the factors?
   - What made them important?
   - If not mentioned by participant, ask specifically whether any of the following factors influenced decision making:
     a. **Symptoms** experienced by the patient;
     b. **Access** to healthcare services (both physical in terms of location of patient to the service and non-physical in terms of the availability of such service);
     c. **Religion**;
     d. Previous **end of life discussions or advance care planning**;
     e. **Previous advice** or guidance provided about healthcare services and utilisation;
     f. **The set-up at home** (e.g. living alone? Married? Children in the house); and
     g. **Previous patterns of consulting behaviour** and **experiences of healthcare services** (including both the ED and elsewhere)

"What things did you weigh-up when deciding that [insert patient's name] needed to visit the ED?"

"You've told me about these important factors that influenced your decision-making [list factors mentioned]. Explain to me why they were important and how they influenced your decision?"

3. Explore hierarchy and relationship between factors mentioned • Was there one factor that was the most important? • Were there factors that were not so important? • Were they related?	**"Were any of these factors you've mentioned more important that others? In what way?"** **"Do you think any of these factors were related to each other? Or are they separate things that you considered individually?"**

Experience at ED and reflecting on decision:

Topic Areas to be Covered	**Example Questions**
1. Explore ED experience further	**"Tell me a bit about what happened when [insert patient name] arrived at the ED?"**
2. Explore previous healthcare utilisation behaviour • Have there been similar situations in the past? • Did they act the same or differently?	**"Has [insert patient name] ever been that unwell before?"**
3. Ask participant to reflect on decision	**"Looking back now, what are your reflections on the experience and decision that was made?** ***OR*** **"If the same situation arose again, what would you do differently?**
4. Explore preferences for acute care services • Would they prefer care at home or in hospital? • Why?	**"If [insert patient's name] needed urgent care again, describe to me what you would consider an ideal service to respond?**

Concluding Interview

1. Remind participant about the study purpose	**The purpose of this study is to try and understand how people with cancer, and their family or friends decide to go to the ED. Are there any areas that we haven't talked about that you feel would be important to discuss?"**
2. Ask for any final thoughts or comments	**"Do you have any questions, final thoughts or comments?"**

---------- STOP RECORDING ----------

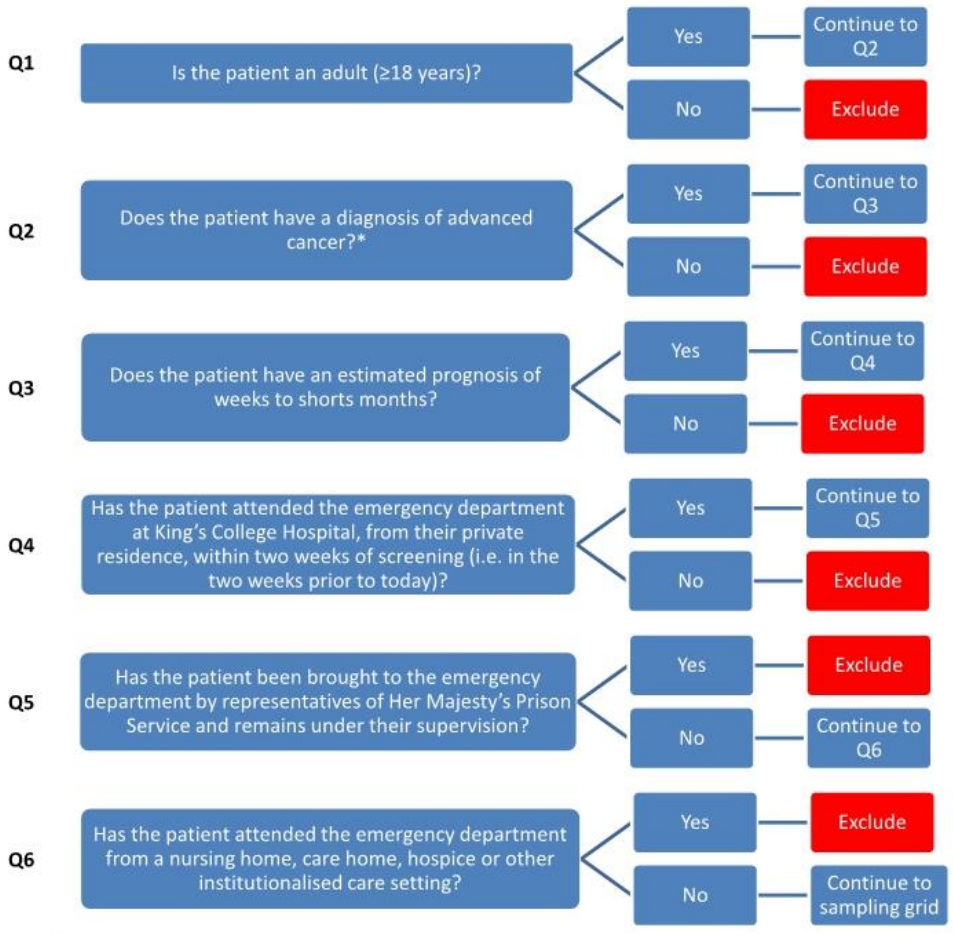
---------- COMPLETE PARTICIPANT DEMOGRAPHICS FORM ----------

Final Tasks:

- Check participant is okay with the interview process and enquire if they would like any additional support at this time. If participant shows any signs of distress refer to Distress Protocol for further action.
- Leave details of the Macmillan Information & Support Centre, based at the Cicely Saunders Institute, King's College Hospital.
- Ask caregiver if they would like a copy of the study findings.
- Thank participant.

Appendix I - Qualitative Interview Study Screening Tool and Sampling Matrix

Patient Participant Screening Tool, King's College Hospital



***Definitions:**

Advanced cancer: cancer that has invaded surrounding body tissues and/ or metastasised and is not curable and is life-threatening

Primary Criteria	Gender		WOMEN												
	Patient under the care of PC prior to ED attendance		YES						NO						
	HCP involved in decision-making		YES			NO			YES			NO			
	Ethnicity		Black	White	Other Ethnic Minority Groups	Black	White	Other Ethnic Minority Groups	Black	White	Other Ethnic Minority Groups	Black	White	Other Ethnic Minority Groups
Secondary & Tertiary Criteria	Type of Cancer	Lung Cancer												
		Other Cancer												
	SES	SES 1-3												
		SES 4-5												
	Age (years)	<60												
		60-80												
		>80												
QUOTA			1	1	1	2	2	2	1	1	1	2	2	2

Primary Criteria	Gender		MEN											
	Patient under the care of PC prior to ED attendance		YES						NO					
	HCP involved in decision-making		YES			NO			YES			NO		
	Ethnicity		Black	White	Other Ethnic Minority Groups	Black	White	Other Ethnic Minority Groups	Black	White	Other Ethnic Minority Groups	Black	White	Other Ethnic Minority Groups
Secondary & Tertiary Criteria	Type of Cancer	Lung Cancer												
		Other Cancer												
	SES	SES 1-3												
		SES 4-5												
	Age (years)	<60												
		60-80												
		>80												
QUOTA			1	1	1	2	2	2	1	1	1	2	2	2